

EXHIBIT D

1 UNITED STATES DISTRICT COURT
2 SOUTHERN DISTRICT OF WEST VIRGINIA
3 AT CHARLESTON
4 -----:
5 IN RE ETHICON, INC., PELVIC :
6 REPAIR SYSTEM PRODUCTS : MASTER FILE
7 LIABILITY LITIGATION : No. 2:12-MD-02327
8 _____
9 : :
10 THIS DOCUMENT RELATES TO : MDL 2327
11 : :
12 WAVE 4 CASES : :
13 TVT and TVT-EXACT : JOSEPH R. GOODWIN
14 : :
15 : US DISTRICT JUDGE
16 -----

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March 12, 2017

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14

CONFIDENTIAL

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Deposition of HARVEY A. WINKLER, M.D.,

held at Butler Snow LLP, 1700 Broadway,

17 New York, commencing at 8:49 a.m., on the

18 above date, before Marie Foley, a Registered

19 Merit Reporter, Certified Realtime Reporter

20 and Notary Public.

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- - -

22

GOLKOW TECHNOLOGIES, INC.

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<p>1 APP E A R A N C E S:</p> <p>2</p> <p>3 ZONIES LAW LLC</p> <p>4 BY: GREG BENTLEY, ESQUIRE</p> <p>5 CHELSEA THOMPSON, ESQUIRE</p> <p>6 1900 Wazee Street, Suite 203</p> <p>7 Denver, Colorado 80202</p> <p>8 720.464.5300</p> <p>9 Representing the Plaintiff</p> <p>10</p> <p>11</p> <p>12</p> <p>13 BUTLER SNOW LLP</p> <p>14 BY: PAUL S. ROSENBLATT, ESQUIRE</p> <p>15 1020 Highland Colony Parkway</p> <p>16 Suite 1400</p> <p>17 Ridgeland, Missouri 39157</p> <p>18 601.948.5711</p> <p>19 paul.rosenblatt@butlersnow.com</p> <p>20 Representing the Defendant</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>1 - - -</p> <p>2 EXHIBITS</p> <p>3 - - -</p> <p>4 NO. DESCRIPTION PAGE</p> <p>5 Winkler 1 Amended Notice to Take 10</p> <p>6 Deposition of Harvey</p> <p>7 Winkler, M.D., dated March</p> <p>8 9, 2017</p> <p>9 Winkler 2 Expert Report of Harvey 10</p> <p>10 Winkler, M.D. Regarding</p> <p>11 TTV and TTV Exact, dated</p> <p>12 February 5, 2017</p> <p>13 Winkler 3 Curriculum Vitae of Harvey 11</p> <p>14 Winkler, M.D.</p> <p>15 Winkler 4 Supplemental General 11</p> <p>16 Reliance List in Addition</p> <p>17 to Materials Referenced in</p> <p>18 Report MDL Wave 4</p> <p>19 Winkler 21 E-mail chain ending August 96</p> <p>20 15, 2001, Bates No.</p> <p>21 ETH.MESH.25126573 through</p> <p>22 ETH.MESH.25126575</p> <p>23</p> <p>24</p>
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1	-----		1	-----
2	E X H I B I T S		2	8:49 a.m.
3	-----		3	New York, New York
4	NO. DESCRIPTION PAGE		4	-----
5	Winkler 18 Power Point slide deck of	169	5	HARVEY A. WINKLER, M.D., the Witness herein,
6	Harvey Winkler, M.D.		6	having been first duly sworn by a
7	Winkler 25 Color copy of photograph	182	7	Notary Public in and of the State of
8	Winkler 26 Shalom article	295	8	New York, was examined and testified as
9	Winkler 27 Unger article	326	9	follows:
10	Winkler 28 Welk article	328	10	EXAMINATION BY
11	Winkler 29 Guideline for the Surgical	332	11	MR. BENTLEY:
12	Management of Female		12	Q. Good morning, Dr. Winkler. My
13	Stress Urinary		13	name is Greg Bentley. We met shortly a
14	Incontinence: 2009 Update		14	couple minutes ago off the record.
15	Winkler 30 Schimpf article	340	15	Do you understand that you're
16	Winkler 31 Ford Cochrane review	341	16	here today for a deposition in the Ethicon
17	Winkler 32 Ethicon Inc. Johnson &	376	17	MDL?
18	Johnson report dated March		18	A. Yes.
19	3, 2003		19	Q. We're going to start this
20			20	morning with a deposition covering your
21			21	TVT and TTVT-Exact report.
22			22	Is that fair?
23			23	A. Fair.
24			24	Q. I'm going to hand you what's

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<p>1 being marked as Exhibit 1, which is notice 2 of your deposition. 3 (Exhibit Winkler 1, Amended 4 Notice to Take Deposition of Harvey 5 Winkler, M.D., dated March 9, 2017, 6 was marked for identification, as of 7 this date.)</p> <p>8 BY MR. BENTLEY:</p> <p>9 Q. Do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. Have you seen that before today, 12 Doctor?</p> <p>13 A. Yes.</p> <p>14 Q. I'm going to hand you what's 15 being marked as Exhibit 2, which I believe 16 is a copy of your TVT and TTVT-Exact 17 report.</p> <p>18 (Exhibit Winkler 2, Expert 19 Report of Harvey Winkler, M.D. 20 Regarding TTVT and TTVT Exact, dated 21 February 5, 2017, was marked for 22 identification, as of this date.)</p> <p>23 BY MR. BENTLEY:</p> <p>24 Q. Is that what that appear to be?</p>	<p>1 Q. You provided the same CV and 2 reliance materials for both your TTVT, 3 TTVT-Exact, Prolift and Gynemesh reports; 4 is that correct?</p> <p>5 A. Yes.</p> <p>6 Q. For the record, we're going to 7 start this afternoon with your deposition 8 that covers your prolapse reports and 9 we'll probably enter the same deposition 10 exhibits that we need for that, okay?</p> <p>11 A. No problem.</p> <p>12 Q. Doctor, have you been deposed 13 before?</p> <p>14 A. Yes.</p> <p>15 Q. How many times have you been 16 deposed before?</p> <p>17 A. Twice, that I recall.</p> <p>18 Q. When was the first deposition 19 that you recall?</p> <p>20 A. That was years ago. I don't 21 remember the name. It was a obstetric 22 case while I was a resident at Einstein.</p> <p>23 Q. And what was the purpose of your 24 deposition, do you remember?</p>
Page 11	Page 13
<p>1 A. Yes.</p> <p>2 Q. And I'm handing you what's being 3 marked as Exhibit 3, which is I believe 4 your CV that was produced with your 5 report.</p> <p>6 (Exhibit Winkler 3, Curriculum 7 Vitae of Harvey Winkler, M.D., was 8 marked for identification, as of this 9 date.)</p> <p>10 BY MR. BENTLEY:</p> <p>11 Q. Is that what that appears to be?</p> <p>12 A. Yes.</p> <p>13 Q. And I'm going to hand you what's 14 being marked as Exhibit 4, which I believe 15 is a copy of your reliance materials that 16 was provided with your report.</p> <p>17 (Exhibit Winkler 4, Supplemental 18 General Reliance List in Addition to 19 Materials Referenced in Report MDL 20 Wave 4, was marked for identification, 21 as of this date.)</p> <p>22 BY MR. BENTLEY:</p> <p>23 Q. Is that fair?</p> <p>24 A. Yes.</p>	<p>1 MR. BENTLEY: That may have been 2 a bad question. Let me rephrase it.</p> <p>3 Q. Were you being deposed as a fact 4 witness?</p> <p>5 A. No.</p> <p>6 Q. Were you a party to the 7 litigation?</p> <p>8 A. Yes, as a resident.</p> <p>9 Q. Was it for a malpractice suit?</p> <p>10 A. Yes.</p> <p>11 Q. And what were the circumstances 12 of that suit?</p> <p>13 A. Goes back way far. It was an 14 obstetric case. I guess it was a bad 15 outcome. I was dropped from the case.</p> <p>16 Q. Today if I ask you a bad 17 question, please just let me know and I'll 18 try and rephrase it. That's entirely 19 possible, or probably more likely.</p> <p>20 Likewise, if you answer the 21 question, is it fair to assume that you 22 understood the question?</p> <p>23 A. Yes.</p> <p>24 Q. And you understand today that</p>

<p style="text-align: right;">Page 14</p> <p>1 you're giving sworn testimony that would 2 be the same full effect as if you were 3 before a judge and a jury?</p> <p>4 A. Yes.</p> <p>5 Q. What was the second deposition 6 that you had?</p> <p>7 A. It was as a fact witness in this 8 MDL.</p> <p>9 Q. And when was that?</p> <p>10 A. About two weeks ago.</p> <p>11 Q. Was that for your treatment of 12 one of the patients?</p> <p>13 A. I was an explanting physician.</p> <p>14 Q. And was that in the Ethicon MDL?</p> <p>15 A. Yes.</p> <p>16 Q. You say you were an explanting 17 physician.</p> <p>18 So you didn't implant the mesh 19 product in that?</p> <p>20 A. No.</p> <p>21 Q. Was that a prolapse or a TVT 22 product that you were explanting?</p> <p>23 A. I don't recall which one I 24 explanted. It was either a TVT product or</p>	<p style="text-align: right;">Page 16</p> <p>1 Q. What was her indication of what 2 complications was she having that 3 necessitated you to do an explant surgery?</p> <p>4 A. She had a urethrovaginal 5 fistula.</p> <p>6 Q. Could you describe what that 7 means?</p> <p>8 A. So, she had a connection or a 9 hole going from her urethra, the urethra 10 is the tube where the urine comes out of, 11 into the vagina.</p> <p>12 Q. And what complications would 13 have manifested from that such that she 14 would end up with you?</p> <p>15 A. So, I don't remember what her 16 particular complications were offhand, but 17 she may have been losing urine. She could 18 have had some urgency and frequency, or 19 just some vaginal bleeding and discomfort.</p> <p>20 Q. And you said that you saw her 21 after the explant surgery.</p> <p>22 How did she progress after you 23 took some of the mesh out?</p> <p>24 A. With regards to my repair, she</p>
<p style="text-align: right;">Page 15</p> <p>1 a Prolift.</p> <p>2 Q. So, your patient had both 3 products, both a prolapse and an 4 incontinence product --</p> <p>5 A. Yes.</p> <p>6 Q. And you removed some mesh, but 7 you don't recall which product it was?</p> <p>8 A. Correct. It was years ago when 9 I removed it before all this MDL stuff 10 started.</p> <p>11 Q. Do you remember approximately 12 when you would have done that explant 13 surgery?</p> <p>14 A. I think it was 2011-ish, 2010, 15 '11, '12. I don't remember the exact date 16 from the chart.</p> <p>17 Q. And where was that deposition?</p> <p>18 A. That was in Garden City at 19 Heidell, Pittoni, Murphy and Bach.</p> <p>20 Q. Have you seen that patient since 21 you did the explant surgery?</p> <p>22 A. So, I saw her subsequently 23 several times after. We have not seen her 24 in a couple years in our practice.</p>	<p style="text-align: right;">Page 17</p> <p>1 did well. The urethrovaginal fistula was 2 healed and the majority of her urinary 3 complaints resolved.</p> <p>4 Q. What about with regard to her 5 discomfort or pain?</p> <p>6 A. Those resolved as well, to my 7 recollection.</p> <p>8 Q. How much mesh did you take out, 9 if you recall?</p> <p>10 A. I think I took out whatever I 11 saw in the urethra at that point in time. 12 Probably it was, I don't know, 1-by-3, 13 1-by-2, somewhere around there. I don't 14 recall.</p> <p>15 Q. Are you talking about 16 centimeters or millimeters?</p> <p>17 A. Centimeters.</p> <p>18 Q. Would that have been blue mesh?</p> <p>19 A. I don't remember the color.</p> <p>20 Q. When you took that mesh out, 21 would you have sent it to pathology?</p> <p>22 A. Yes.</p> <p>23 Q. And what tests would you have 24 requested that pathology perform?</p>

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<p>1 A. They just did a gross look-see 2 at it. They didn't comment on the color, 3 once again before all this MDL started, to 4 document that.</p> <p>5 Q. And did the gross examination 6 have any findings that you remember?</p> <p>7 A. No significant findings, that I 8 recall.</p> <p>9 Q. So, on Exhibit 2, Doctor, which 10 is your report.</p> <p>11 A. Okay.</p> <p>12 Q. It appears it's 61 pages and at 13 the end are almost 200 footnotes; is that 14 correct?</p> <p>15 A. Correct.</p> <p>16 Q. And those are citations to facts 17 you discussed in your report; is that 18 correct?</p> <p>19 A. Correct.</p> <p>20 Q. But you're reliance list shows 21 that you reviewed several more articles 22 than that, obviously, right?</p> <p>23 A. Correct.</p> <p>24 Q. On page 53 it indicates that you</p>	<p>1 the positive, as well as to write the 2 scientific data that I was aware of 3 backing those claims.</p> <p>4 Q. Okay. And does this report 5 include a complete list of all the 6 opinions you intend to offer at trial?</p> <p>7 A. I always reserve the right to 8 add additional opinions.</p> <p>9 Q. As you sit here today, do you 10 have any additional opinions that you 11 intend to offer at trial?</p> <p>12 A. Not that I'm aware of today.</p> <p>13 Q. And does this report contain a 14 complete list of the bases for your 15 opinions included within the report?</p> <p>16 A. Yes.</p> <p>17 Q. Do you still stand by all of 18 your opinions in this report?</p> <p>19 A. Yes.</p> <p>20 Q. Are there any changes you would 21 like to make to this report at this 22 moment?</p> <p>23 A. No. Unless we find a typo here 24 and there.</p>
Page 19	Page 21
<p>1 signed off on the report on February 5th, 2 2017.</p> <p>3 Do you see that?</p> <p>4 A. Correct.</p> <p>5 Q. And is that accurate?</p> <p>6 A. Yes.</p> <p>7 Q. When did you write this report, 8 Doctor?</p> <p>9 A. My gosh, I spent all, like, 10 December and January writing these 11 reports. My wife said, "When are you 12 coming back to visit the family?"</p> <p>13 I spent the entire holiday weeks 14 writing the reports, weekends, nights, 15 days, all December and January literally.</p> <p>16 Q. Right. And what was your -- how 17 did you go about deciding what to write? 18 What was your technique that you might 19 have done this, if you can describe?</p> <p>20 A. Well, I wanted to tell a little 21 bit about myself and how I got to where I 22 was and then to write about why I think 23 the TVT product has really made a 24 difference in many women's lives as -- for</p>	<p>1 Q. It's a long report. 2 Let's look at what I believe was 3 marked as Exhibit 3, which is your CV.</p> <p>4 A. Okay.</p> <p>5 Q. Did you prepare this CV?</p> <p>6 A. Yes.</p> <p>7 Q. And is this a true and accurate 8 reflection of your professional 9 experience?</p> <p>10 A. Yes.</p> <p>11 Q. Did you make this CV for this 12 case?</p> <p>13 A. No.</p> <p>14 Q. This is your CV you've used in 15 your normal day-to-day professional 16 activities?</p> <p>17 A. Yes, and it may get updated 18 every month, every two months, whatever. 19 You know, whenever I do something, I try 20 to put it in to try to keep track.</p> <p>21 Q. You add new information as you 22 have new items to add?</p> <p>23 A. Correct.</p> <p>24 Q. So your CV contains your</p>

<p style="text-align: right;">Page 22</p> <p>1 education, your training, your 2 publications, things like that? 3 A. Correct. 4 Q. And do you remember the last 5 time you updated this CV? 6 A. I think the last update that I 7 did, this is it. I haven't updated it 8 since. I'll probably do an update in 9 about a month. 10 Q. Do you have something you intend 11 to update it with? 12 A. Going to Australia to be a 13 national speaker in their urogynecological 14 annual conference. 15 Q. Other than that, are there any 16 things missing or that you would like to 17 change in your CV? 18 A. No, nothing missing. We've 19 submitted other publications, so if they 20 get accepted, I would add them. 21 Q. And likewise there's nothing you 22 need to take out or that you know of 23 that's incorrect in there? 24 A. Correct.</p>	<p style="text-align: right;">Page 24</p> <p>1 Q. Do you have anything you intend 2 to supplement it with that you know of? 3 A. The reliance list, no. We did 4 bring -- 5 THE WITNESS: Should we take 6 that picture out? 7 MR. ROSENBLATT: (Handing.) 8 MR. BENTLEY: This is what 9 you're talking about? 10 THE WITNESS: Yes. 11 That's the one we brought, 12 right? 13 MR. ROSENBLATT: Greg, there's 14 another picture I need to get printed. 15 MR. BENTLEY: We can do it at a 16 break. 17 BY MR. BENTLEY: 18 Q. Doctor, can you please describe 19 for me a little bit about your education, 20 where you went to school and when? 21 A. Sure. Sure. 22 Q. And if you want to review your 23 CV. 24 A. No, it's just for the date.</p>
<p style="text-align: right;">Page 23</p> <p>1 Q. Do you have multiple versions of 2 your CV that you would use for different 3 purposes? 4 A. This is pretty much the one I 5 like -- I stand to use today. I try to 6 send this one out. 7 Q. Looking at Exhibit 3 which we 8 entered, which I believe is your reliance 9 list, is this a complete list as you sit 10 here today of all the reliance materials 11 you've reviewed -- 12 A. I have Exhibit 4. 13 Q. I'm sorry, 4. Thank you. That 14 will probably happen again. 15 A. That's okay. As long as we're 16 looking at the same thing. 17 Q. So, is this reliance list, as 18 you sit here today, a complete and 19 accurate list of materials you relied upon 20 in reaching your opinions in this case? 21 A. Yes. 22 Q. Is there anything that you would 23 like to add or take out of it today? 24 A. Not right now.</p>	<p style="text-align: right;">Page 25</p> <p>1 This way I don't have to memorize the 2 dates and whatnot. Although I know them. 3 I did live them. 4 In 1988 I graduated from Yeshiva 5 University with a BA. In 1992 I graduated 6 from the Albert Einstein College of 7 Medicine. I then did a residency from '92 8 to '96 also at the Albert Einstein College 9 of Medicine in obstetrics and gynecology. 10 From '96 to '98 I did a fellowship in 11 urogynecology, what is now known as female 12 pelvic medicine and reconstructive 13 surgery, at Evanston Hospital in Chicago 14 under Peter Sand. From '98 to 2002 I 15 worked at the Maimonides Medical Center as 16 the director of the division of 17 urogynecology there. 18 Q. Where is that? 19 A. That's in Brooklyn, New York. 20 Q. Okay. 21 A. And then from 2002 to present 22 day I've worked at North Shore LIJ, which 23 is known as Northwell Health. I'm 24 the co-chief of division of urogynecology</p>

<p style="text-align: right;">Page 26</p> <p>1 there. I'm the program director for the 2 fellowship in female pelvic medicine and 3 reconstructive surgery there. I'm an 4 associate professor at the Hofstra 5 Northwell School of Medicine.</p> <p>6 Q. What courses do you teach?</p> <p>7 A. So, I don't teach any courses in 8 the medical school. I teach residents in 9 the hospital, medical students as well as 10 the fellowship program. I manage and 11 direct that.</p> <p>12 Q. The medical school students that 13 you teach, is that just general medical, 14 or have they specialized at that point?</p> <p>15 A. Excuse me?</p> <p>16 Q. What do you teach the medical 17 school students?</p> <p>18 A. So, medical students, generally 19 I would teach them surgical principles. I 20 would have the most -- they don't come to 21 our office, but they come to the operating 22 rooms with us and give them the first 23 introduction to surgical principles, risks 24 and benefits of surgeries that we perform.</p>	<p style="text-align: right;">Page 28</p> <p>1 bladder pain syndromes. We'll treat 2 complications after pregnancy, vaginal 3 complications. We'll treat recurrent 4 urinary tract infections. We'll treat 5 symptoms of vaginal atrophy. Some of us 6 will deal with sexual dysfunction, 7 although I don't deal very much with 8 sexual dysfunction, and we also will deal 9 with complications regarding the bladder 10 and/or vagina from surgery, so surgical 11 postoperative surgical complications that 12 can occur.</p> <p>13 Q. You said "some of us will treat 14 sexual dysfunction."</p> <p>15 How many other doctors are in 16 your group?</p> <p>17 A. So, we have in the immediate 18 practice where I practice we have two 19 other physicians, two other attendings. 20 We have three nurse practitioners and we 21 also have the fellows. We have another -- 22 Northwell has another practice out east 23 with another doctor that we also work with 24 with the fellowship program, but there's</p>
<p style="text-align: right;">Page 27</p> <p>1 Q. Is that specific to 2 urogynecological surgeries, or is that 3 just general surgical principles?</p> <p>4 A. Well, they're general surgical 5 principles in urogynecologic surgery, but 6 we would then discuss specific to 7 urogynecology.</p> <p>8 Q. And likewise you're seeing 9 fellows or students in the fellowship 10 program, what emphasis are you -- what 11 surgical knowledge or what emphasis are 12 you teaching them?</p> <p>13 A. Well, there's certain basic 14 knowledge that I teach them always about 15 surgical principles. We treat the whole 16 body, not just the pelvis, but we do 17 specialize on the pelvis or complications 18 that can occur or pathology that can occur 19 with female pelvic disorders.</p> <p>20 Q. And what female pelvic disorders 21 do you treat?</p> <p>22 A. So, I treat the main two that we 23 treat are urinary incontinence and pelvic 24 organ prolapse. However, we'll also treat</p>	<p style="text-align: right;">Page 29</p> <p>1 no intermingling of patients from those 2 other practices.</p> <p>3 Q. When you treat stress urinary 4 incontinence or incontinence generally, 5 what are the treatment options that you 6 would normally go through for any 7 particular patient?</p> <p>8 A. So, for stress urinary 9 incontinence, after our history and 10 physical examination, we have a discussion 11 about what -- I explain to them what the 12 problem is and what the situation is, and 13 we'd also have a discussion about 14 treatment options.</p> <p>15 First and foremost, every 16 patient is told that she can do nothing, 17 this is not a life-and-death situation; 18 it's a quality-of-life situation. So she 19 can do nothing. Obviously they're there 20 for a reason. They're not there to do 21 nothing, but they do get all told that.</p> <p>22 Then we will talk about 23 behavioral modification and/or Kegel 24 exercises associated with it. We'll talk</p>

<p style="text-align: right;">Page 30</p> <p>1 about intravaginal devices or occlusive 2 devices, pessaries, vaginal inserts that 3 are options. We'll talk about off-label 4 use of medications. We'll also then talk 5 about surgical options. We'll talk about 6 midurethral slings.</p> <p>7 Q. I'm sorry to interrupt you. 8 When you're talking about 9 surgical options, you're starting to 10 delineate what the options are in that 11 category?</p> <p>12 A. Correct.</p> <p>13 Q. So, the first one you said was 14 midurethral slings?</p> <p>15 A. Midurethral slings.</p> <p>16 Q. What other surgical options do 17 you have?</p> <p>18 A. We have Burch procedures and 19 autologous pubovaginal slings and 20 periurethral bulking.</p> <p>21 Q. When you were in medical school 22 and your fellowship, what incontinence 23 procedures were available that you were 24 trained on?</p>	<p style="text-align: right;">Page 32</p> <p>1 procedures.</p> <p>2 Q. And who is Dr. Vincent Lucente?</p> <p>3 A. He was one of the preceptors for 4 Gynecare in 1999 when I learned how to do 5 the procedure.</p> <p>6 Q. Do you have an understanding of 7 whether Dr. Vincent Lucente works for 8 Ethicon or worked for Ethicon?</p> <p>9 MR. ROSENBLATT: Object to form.</p> <p>10 Q. You can answer.</p> <p>11 A. He was a consultant. He wasn't 12 a employee of Ethicon.</p> <p>13 Q. He was getting paid by Ethicon.</p> <p>14 A. I know.</p> <p>15 Q. Can you describe for me what a 16 pubovaginal sling is made of?</p> <p>17 A. So, there are different types of 18 pubovaginal slings. There's autologous 19 pubovaginal slings which is where we 20 harvest or take a piece of tissue from the 21 patient that we're operating on. So it's 22 their own tissues.</p> <p>23 Q. And what part of the body do you 24 harvest that from?</p>
<p style="text-align: right;">Page 31</p> <p>1 A. So, in my fellowship I was 2 trained on Kelly-Keenedy plications, 3 anterior repairs, which nobody really does 4 today. For stress urinary incontinence 5 procedures, that was my primary teaching 6 in residency. In fellowship my primary 7 education was in Burch procedures and 8 pubovaginal slings and we did periurethral 9 bulking back then too.</p> <p>10 Q. And your fellowship was 1996 to 11 1998?</p> <p>12 A. Correct.</p> <p>13 Q. Then subsequently to your 14 fellowship, the midurethral slings came to 15 market and you learned how to implant 16 those, correct?</p> <p>17 A. Correct.</p> <p>18 Q. And how did you learn to implant 19 midurethral slings like the TVT?</p> <p>20 A. So, I was familiar already with 21 placing in pubovaginal slings. I went to 22 Philadelphia to talk and observe Dr. 23 Vincent Lucente, who had learned the 24 procedure, and after that I performed the</p>	<p style="text-align: right;">Page 33</p> <p>1 A. Fascia lata which is a strip of 2 fascia from the thigh.</p> <p>3 Then there are slings that you 4 can use from other humans, cadaveric 5 slings, so there was cadaveric tissue 6 slings that you can use, autografts. And 7 then there's something, xenografts which 8 are tissues from other animals.</p> <p>9 Q. And what animals would you 10 harvest from using -- or what --</p> <p>11 A. I get the question.</p> <p>12 Q. Let me just get the question 13 out.</p> <p>14 What products are sold that are 15 xenografted?</p> <p>16 A. So, some products have been on 17 the market and then have left. There was 18 porcine dermis that was on the market.</p> <p>19 Q. Is that Pelvicol?</p> <p>20 A. Yes, Pelvicol.</p> <p>21 Today you would use there's 22 bovine fetal pericardium, which is 23 something called Xenform, that you can go 24 ahead and use.</p>

<p style="text-align: right;">Page 34</p> <p>1 Q. Who makes Xenform?</p> <p>2 A. Xenform, I don't know who makes</p> <p>3 it, but Boston Scientific is the company</p> <p>4 that you would buy it from, but another</p> <p>5 companies harvests it.</p> <p>6 Q. Sometimes those are referred to</p> <p>7 as biologics?</p> <p>8 A. Correct.</p> <p>9 Q. And do you use biologics today?</p> <p>10 A. I've used biologics in the past.</p> <p>11 I haven't used biologics in the past</p> <p>12 several years for vaginal surgeries.</p> <p>13 Q. Did you have bad results with</p> <p>14 biologics?</p> <p>15 A. Biologics have not been shown to</p> <p>16 really give you good long-term efficacy</p> <p>17 for slings.</p> <p>18 Q. Are you talking about the</p> <p>19 literature or in your personal experience?</p> <p>20 A. In the literature.</p> <p>21 Q. So in your personal experience,</p> <p>22 you had good results with biologics?</p> <p>23 A. I would say my experience was</p> <p>24 consistent with the literature.</p>	<p style="text-align: right;">Page 36</p> <p>1 Q. How many patients do you treat</p> <p>2 on average a week or a month, if you have</p> <p>3 an estimate?</p> <p>4 A. I see approximately, me</p> <p>5 personally and not the nurse practitioners</p> <p>6 who see patients, I probably see about 50</p> <p>7 to 60 patients a week.</p> <p>8 Q. And how many surgical procedures</p> <p>9 do you estimate you do in a week?</p> <p>10 A. A week, I don't know. I do</p> <p>11 something -- at this point, I think I do</p> <p>12 somewhere around 200, 225, somewhere</p> <p>13 around the 200.</p> <p>14 Q. Per year?</p> <p>15 A. Per year, yeah. 225, somewhere</p> <p>16 in there.</p> <p>17 Q. And approximately how many</p> <p>18 procedures do you think you're performing</p> <p>19 a year for incontinence, or to treat</p> <p>20 incontinence?</p> <p>21 A. The majority of my patients I'm</p> <p>22 treating with incontinence one way or the</p> <p>23 other. 175, 200. 175-ish.</p> <p>24 Q. I'm just trying to get an idea.</p>
<p style="text-align: right;">Page 35</p> <p>1 Q. So we went through the</p> <p>2 pubovaginal slings, Burch.</p> <p>3 You still do Burch today?</p> <p>4 A. I still do Burch procedures. I</p> <p>5 offer Burch procedures. I don't do as</p> <p>6 many as I used to in the past, but it's a</p> <p>7 procedure that I am entirely comfortable</p> <p>8 with performing.</p> <p>9 Q. Are there different types of</p> <p>10 Burch procedure?</p> <p>11 A. I do the Tanagho modification of</p> <p>12 the Burch procedure and then there are</p> <p>13 different ways that people -- not</p> <p>14 different ways, but different sutures that</p> <p>15 people may use for the Burch procedure. I</p> <p>16 prefer a 2-0 Gore-Tex suture and I put two</p> <p>17 sutures on each side. The Burch procedure</p> <p>18 really works with scarring. So you want</p> <p>19 to try to increase the scarring that</p> <p>20 occurs in the retropubic space. So I also</p> <p>21 put little pieces of gel foam underneath</p> <p>22 the suture bridges to try to increase the</p> <p>23 scarring that takes place in order to give</p> <p>24 longevity to the procedure.</p>	<p style="text-align: right;">Page 37</p> <p>1 A. Yeah, you know, listen, I</p> <p>2 haven't looked at these numbers in a long</p> <p>3 time.</p> <p>4 Q. Do you treat men and women?</p> <p>5 A. No, just women.</p> <p>6 Q. Of the 175 women that you do</p> <p>7 surgery on per year for incontinence,</p> <p>8 approximately how many of those would you</p> <p>9 estimate are Burch procedure?</p> <p>10 A. Zero to 1.</p> <p>11 Q. So, the majority -- what</p> <p>12 procedure are you performing on the 175</p> <p>13 women to treat incontinence?</p> <p>14 A. Midurethral slings.</p> <p>15 Q. And what kind of slings are you</p> <p>16 using?</p> <p>17 A. So, I use retropubic slings. I</p> <p>18 use transobturator slings, as well as the</p> <p>19 mini sling.</p> <p>20 Q. Which retropubic sling are you</p> <p>21 using today?</p> <p>22 A. So, I use TTVT-Exact as well as</p> <p>23 the Boston Scientific Advantage.</p> <p>24 Q. You don't currently use the</p>

<p style="text-align: right;">Page 38</p> <p>1 TTVT-R, the classic TTVT Retropubic?</p> <p>2 A. No.</p> <p>3 Q. Then you said you're also using</p> <p>4 the Boston Scientific Advantage?</p> <p>5 A. Mm-hm.</p> <p>6 Q. One of the other things is we</p> <p>7 need to have audible answers so Marie can</p> <p>8 get the transcript down.</p> <p>9 A. Was I not talking loud enough?</p> <p>10 Q. You said "mm-hm."</p> <p>11 So one of the retropubic slings</p> <p>12 you're using today was the Boston</p> <p>13 Scientific Advantage, correct?</p> <p>14 A. Correct.</p> <p>15 Q. And you have both of those</p> <p>16 slings available for you in your operating</p> <p>17 room for you to choose from?</p> <p>18 A. Correct.</p> <p>19 Q. And how do you decide with any</p> <p>20 given patient if you want to use the</p> <p>21 TTVT-Exact or the Boston Scientific</p> <p>22 Advantage?</p> <p>23 A. To be honest with you, I think</p> <p>24 they're very similar.</p>	<p style="text-align: right;">Page 40</p> <p>1 stick with one company at this point in</p> <p>2 time, use the same meshes. So if I'm</p> <p>3 doing, let's say, a sacrocolpopexy or</p> <p>4 anything like that, then I would go ahead</p> <p>5 and use the Boston Scientific mesh. I</p> <p>6 don't have a personal preference over one</p> <p>7 or the other. I think they're both</p> <p>8 excellent slings and function pretty much</p> <p>9 the same way and pretty much placed in the</p> <p>10 same way.</p> <p>11 Q. So you have no preference one</p> <p>12 way or the other of which sling you're</p> <p>13 using?</p> <p>14 A. I don't think one is better than</p> <p>15 the other, absolutely not.</p> <p>16 Q. What percentage of your women</p> <p>17 that you treat for incontinence do you</p> <p>18 think you use the retropubic sling?</p> <p>19 A. Thirty percent.</p> <p>20 Q. So, since slings have been</p> <p>21 available, have you changed the product</p> <p>22 that you use? Or, which products --</p> <p>23 MR. BENTLEY: Let me strike</p> <p>24 that.</p>
<p style="text-align: right;">Page 39</p> <p>1 One of the things that we're</p> <p>2 required to notify our patients of,</p> <p>3 because of this MDL, is the recent</p> <p>4 allegations against Boston Scientific that</p> <p>5 it's a counterfeit mesh. So if a patient</p> <p>6 doesn't want a Boston Scientific mesh,</p> <p>7 then I can use a TTVT-Exact.</p> <p>8 Q. So your initial recommendation</p> <p>9 is going to be Boston Scientific</p> <p>10 Advantage, but you're going to present to</p> <p>11 them that there's been some issues</p> <p>12 potentially with the mesh and if they are</p> <p>13 concerned about that, then you go to</p> <p>14 TTVT-Exact? Is that a fair statement?</p> <p>15 MR. ROSENBLATT: Objection to</p> <p>16 form.</p> <p>17 A. No.</p> <p>18 Q. Let's start with how do you</p> <p>19 decide between TTVT-Exact or Boston</p> <p>20 Scientific Advantage if you're going to</p> <p>21 recommend the retropubic sling for</p> <p>22 patients with incontinence?</p> <p>23 A. So, if I'm doing it together</p> <p>24 with another prolapse surgery, I prefer to</p>	<p style="text-align: right;">Page 41</p> <p>1 Q. Which TTVT retropubic slings have</p> <p>2 you used throughout your career?</p> <p>3 A. So, the majority of them have</p> <p>4 been TTVT and Boston Scientific.</p> <p>5 Q. Okay.</p> <p>6 A. I have passed the AMS sling</p> <p>7 retropubically. They have the SPARC when</p> <p>8 it came out I guess 15 years ago and then</p> <p>9 they had a modification where they had a</p> <p>10 bottom-up. So I've used AMS or Astora's</p> <p>11 slings. I've also used maybe once or</p> <p>12 twice a Caldera sling retropubically.</p> <p>13 Q. And you said you've used some</p> <p>14 biologics.</p> <p>15 Are retropubic slings available</p> <p>16 in biologic mesh?</p> <p>17 A. There's tissue that's available</p> <p>18 in biologics that you can go ahead and</p> <p>19 use. I don't know if they have a specific</p> <p>20 indication for pubovaginal slings in terms</p> <p>21 of biologics, but once again, I said I</p> <p>22 don't really use biologics for my slings</p> <p>23 because of the efficacy.</p> <p>24 Q. So we talked about approximately</p>

<p style="text-align: right;">Page 42</p> <p>1 30 percent of the women you treat for 2 incontinence and that you use slings for a 3 year, about 30 percent of those are 4 retropubic. 5 Approximately how many of the 6 175 sling procedures that you're doing are 7 obturator? 8 A. Today, so things have shifted a 9 little, but today probably another 30 to 10 40 percent are transobturator. Probably 11 about, you know, 40 percent. 12 Q. And what are the advantages with 13 an -- 14 A. Forty-five, somewhere around 15 there. 16 Q. Maybe a little bit more than 17 your retropubic? 18 A. Maybe slightly more, yes. 19 Q. What are some of the advantages 20 of having an obturator-based approached 21 versus the retropubic? 22 A. So, the obturator approach has a 23 little less voiding dysfunction and lower 24 incidence of bladder perforation, not</p>	<p style="text-align: right;">Page 44</p> <p>1 the Ethicon obturator sling? 2 A. I've always liked the outside-in 3 procedure of placing the transobturator 4 sling. I never had a problem with the 5 meshes. And as you heard me say before, I 6 think they're very, very similar. It's 7 just in terms of the way I was taught and 8 the way in my hands and I think it's a 9 little easier to teach as well, so I use 10 the transobturator sling outside-in. 11 Q. We've talked about a couple of 12 different retropubic slings and obturator 13 slings, and those are all 14 polypropylene-based slings, right? 15 A. Correct. 16 Q. But as we've already discussed, 17 there's some advantages to the design of 18 some of the slings versus other slings; is 19 that correct? 20 A. Correct. 21 Q. Have you ever used any of the 22 Ethicon obturator slings? 23 A. No, not that I recall. 24 Q. And then the third type of sling</p>
<p style="text-align: right;">Page 43</p> <p>1 zero, but lower incidence, and it also 2 takes away the risk of bowel perforation. 3 Those are the main ones. 4 Q. Do you tell your patients the 5 risks and benefits of retropubic versus 6 obturator approaches? 7 A. Absolutely. 8 Q. Because ultimately it's the 9 patient's decision on whether she wants to 10 undergo this procedure and take the risk 11 to get the benefits, right? 12 A. I agree with you a hundred 13 percent. 14 And each of my patients gets 15 literature on the procedures. They get 16 information on their stress incontinence, 17 and they ultimately decide whether or not 18 they want to go to the operating room to 19 undergo this procedure. 20 Q. And which obturator slings are 21 you using? 22 A. Today mostly Boston Scientific 23 Obtryx. 24 Q. Is there a reason you don't use</p>	<p style="text-align: right;">Page 45</p> <p>1 that you're using is the mini sling; is 2 that correct? 3 A. Correct. 4 Q. And which mini sling are you 5 using? 6 A. Boston Scientific Solyx. 7 Q. So that would be approximately 8 another 30 to 40 percent, is that fair? 9 A. I think it's probably closer to 10 about 20 percent right now. I've recently 11 been using slightly more of the mini 12 slings as data has come out regarding 13 their efficacy. 14 Q. And what would be the advantage 15 to using a mini sling? 16 MR. ROSENBLATT: Object to form. 17 Q. You can answer. 18 A. As compared to the 19 transobturator sling, I think an advantage 20 is the decreased possibility of developing 21 groin pain. 22 Q. Have you, in your experience 23 using mini slings, have you noticed any 24 advantages to using the mini sling versus</p>

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<p>1 the other slings we've discussed?</p> <p>2 A. Besides the groin pain, no.</p> <p>3 Q. The groin pain is associated</p> <p>4 with mini sling -- let me just clean this</p> <p>5 up.</p> <p>6 Doctor, you said that you're</p> <p>7 using approximately 25 to 30 percent mini</p> <p>8 slings today; is that correct?</p> <p>9 A. Something like that, yeah.</p> <p>10 Q. In your experience using those</p> <p>11 slings, have you used any --</p> <p>12 MR. ROSENBLATT: Object to form.</p> <p>13 I think he said 20 percent. I just</p> <p>14 wanted to make that clear.</p> <p>15 MR. BENTLEY: Okay.</p> <p>16 A. Twenty percent.</p> <p>17 Q. Doctor, in your experience using</p> <p>18 mini slings today, have you noticed any</p> <p>19 benefit to using those slings versus the</p> <p>20 obturator or retropubic slings we already</p> <p>21 discussed?</p> <p>22 A. So, I would use the mini sling</p> <p>23 in place of patients who in the past I</p> <p>24 would have put a transobturator sling in.</p>	<p>1 incontinence, but I'm doing a prolapse</p> <p>2 repair on them and then as part of our</p> <p>3 evaluation for the prolapse repair, we've</p> <p>4 identified that there's a good possibility</p> <p>5 that these patients are going to leak</p> <p>6 postoperatively from stress incontinence.</p> <p>7 So I'm using the mini sling in the</p> <p>8 majority of my patients, not all, majority</p> <p>9 of patients who would have occult stress</p> <p>10 incontinence.</p> <p>11 Q. So you are implanting a sling in</p> <p>12 women prophylactically during a prolapse</p> <p>13 procedure with the anticipation that she</p> <p>14 may develop incontinence later?</p> <p>15 A. No, that's not correct. That's</p> <p>16 not prophylactic. A prophylactic</p> <p>17 procedure is in a patient who would not</p> <p>18 leak with reduction of her prolapse.</p> <p>19 So these patients have stress</p> <p>20 incontinence. It's just being masked by</p> <p>21 their prolapse.</p> <p>22 So, I am not a fan of putting in</p> <p>23 prophylactic slings.</p> <p>24 Q. That would be inappropriate?</p>
<p>1 The data is consistent out there right now</p> <p>2 with mini slings as compared to</p> <p>3 transobturator slings. It would be</p> <p>4 unusual for me to replace a retropubic</p> <p>5 sling with a mini sling for the patients</p> <p>6 that I use retropubic slings on.</p> <p>7 Q. That wasn't really my question.</p> <p>8 My question is you're using a</p> <p>9 mini sling today, correct?</p> <p>10 A. Correct.</p> <p>11 Q. And in your experience using the</p> <p>12 mini sling, have you noticed any</p> <p>13 advantages to using that sling versus a</p> <p>14 full-length sling?</p> <p>15 A. I wouldn't use the mini sling in</p> <p>16 the same patient I use the full-length</p> <p>17 sling in.</p> <p>18 Q. So you have no reason to use</p> <p>19 a -- why are you using a mini sling then?</p> <p>20 A. Okay. So, my mini sling</p> <p>21 patients, more commonly I'm putting them</p> <p>22 in patients who have occult stress</p> <p>23 incontinence. These are patients who do</p> <p>24 not have complaints of stress</p>	<p>1 Page 47</p> <p>1 MR. ROSENBLATT: Object to form.</p> <p>2 BY MR. BENTLEY:</p> <p>3 Q. Do you have an opinion on</p> <p>4 whether or not it would be inappropriate</p> <p>5 to put a sling in during a prolapse</p> <p>6 procedure if the woman wasn't currently</p> <p>7 suffering from incontinence?</p> <p>8 A. Well, there's a risk for them</p> <p>9 developing urinary incontinence after the</p> <p>10 procedure. So I think it's inappropriate.</p> <p>11 I think this is a discussion</p> <p>12 that you need to have with your patient of</p> <p>13 whether or not the patient wants to take</p> <p>14 on the risks of the additional surgery.</p> <p>15 Any time you do surgery there are risks.</p> <p>16 So you have a discussion with the patient</p> <p>17 if they want to take on the risks of the</p> <p>18 procedure for the 25 or 30 percent chance</p> <p>19 that they may lose urine after the surgery</p> <p>20 and whether or not it would be</p> <p>21 symptomatic.</p> <p>22 Q. Do you recommend putting a sling</p> <p>23 in prophylactically during prolapse if</p> <p>24 she's not currently suffering from</p>

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<p>1 incontinence?</p> <p>2 A. I never recommend putting in any</p> <p>3 of these products. It's ultimately the</p> <p>4 patient's decision deciding whether or not</p> <p>5 they want to undergo the procedure.</p> <p>6 Q. And going back to the</p> <p>7 retropubic.</p> <p>8 You said that, I believe you</p> <p>9 said you use Boston Scientific Advantage</p> <p>10 if you're also doing the abdominal</p> <p>11 sacrocolpopexy; is that correct?</p> <p>12 A. Correct.</p> <p>13 Q. And if you're not doing the</p> <p>14 abdominal sacrocolpopexy or ASC, are there</p> <p>15 other situations where you would use the</p> <p>16 Boston Scientific Advantage retropubic</p> <p>17 sling?</p> <p>18 A. So, I can use the TVT or the</p> <p>19 Boston Scientific Advantage if I'm just</p> <p>20 putting in a sling. It doesn't really</p> <p>21 matter. It depends on -- I don't have a</p> <p>22 preference for one over the other.</p> <p>23 Q. What percent of the women where</p> <p>24 you're putting a retropubic sling in are</p>	<p>1 Scientific Solyx that you put in?</p> <p>2 A. I think it's 9 centimeters.</p> <p>3 Q. And do you know what the length</p> <p>4 of the full-length slings are?</p> <p>5 A. Well, so, out of the box, I</p> <p>6 don't recall. Maybe it's 24.</p> <p>7 Don't quote me on that.</p> <p>8 Q. Right.</p> <p>9 A. But we cut the slings. So</p> <p>10 depending on how big the patient is will</p> <p>11 depend on how much sling gets implanted.</p> <p>12 Q. When the sling's implanted, when</p> <p>13 the retropubic sling's implanted, what's</p> <p>14 the general length it's implanted in the</p> <p>15 woman's body?</p> <p>16 MR. ROSENBLATT: Object to form.</p> <p>17 Q. From your experience.</p> <p>18 A. Probably, if I'd have to guess,</p> <p>19 somewhere around 18 centimeters.</p> <p>20 No one's ever asked me that</p> <p>21 question before.</p> <p>22 Q. Do you have an idea how much</p> <p>23 mesh you're trimming off, on average</p> <p>24 usually that's left over?</p>
<p>1 you also doing a ASC repair, if you have</p> <p>2 an estimate?</p> <p>3 A. I do about six to eight ASC</p> <p>4 repairs a month. I would say 90 to 95 get</p> <p>5 a sling, 90 percent.</p> <p>6 Q. So, 90, 95 percent of your ASC</p> <p>7 repairs also get a sling?</p> <p>8 A. Yeah.</p> <p>9 Q. And so those would be the women</p> <p>10 that would also get the Boston Scientific</p> <p>11 Advantage because you want to use the same</p> <p>12 company's product?</p> <p>13 A. Yeah, they would either get an</p> <p>14 Advantage, an Obtryx or a Mini Sling.</p> <p>15 Truthfully, the largest player</p> <p>16 in the space right now and supporting the</p> <p>17 space is Boston Scientific.</p> <p>18 Q. The third category of slings we</p> <p>19 were discussing called mini slings, do you</p> <p>20 have an understanding of why they're</p> <p>21 called mini slings?</p> <p>22 A. They're shorter-length slings</p> <p>23 than the traditional full-length slings.</p> <p>24 Q. What's the length of the Boston</p>	<p>1 A. (Indicating.)</p> <p>2 Q. About six centimeters, is that</p> <p>3 consistent with your --</p> <p>4 A. We're taking off, I guess, about</p> <p>5 six on each side.</p> <p>6 Q. Is it fair to say that generally</p> <p>7 you think the mini sling has half as much</p> <p>8 mesh as the --</p> <p>9 MR. BENTLEY: Strike that.</p> <p>10 Q. Is it fair to say you think the</p> <p>11 length of the retropubic full-length sling</p> <p>12 is about twice as long as the mini sling?</p> <p>13 A. Yeah, we can say that.</p> <p>14 Q. Do you have an understanding of</p> <p>15 why companies would introduce slings that</p> <p>16 are smaller or mini?</p> <p>17 MR. ROSENBLATT: Object to form.</p> <p>18 A. I think they wanted to reduce</p> <p>19 the incidence of the groin pain or some of</p> <p>20 the complications that were occurring with</p> <p>21 the full-length slings.</p> <p>22 Q. You said, I think, the mini</p> <p>23 sling that you use is an obturator-based</p> <p>24 approach?</p>

<p style="text-align: right;">Page 54</p> <p>1 A. Yeah, they're all -- yeah, it's 2 an obturator-based approach. That's what 3 I use it interchangeably for the 4 implanting is slightly different than an 5 obturator approach because I would do the 6 outside-in for the obturator and the mini 7 sort of is inside going into the obturator 8 muscle.</p> <p>9 Q. So you're using a mini version 10 of the Ethicon TVT-O which is inside-out?</p> <p>11 MR. ROSENBLATT: Object to form.</p> <p>12 A. I think I need to explain the 13 procedure a little.</p> <p>14 Q. Let me give you a question. 15 So, the Boston Scientific Obtryx 16 is an outside-in, right?</p> <p>17 A. Yes.</p> <p>18 Q. And then the mini sling that 19 you're using is an obturator-based 20 approach, correct?</p> <p>21 A. Theoretically, yeah.</p> <p>22 Q. But it's inside-out?</p> <p>23 A. Inside-out, yeah.</p> <p>24 Q. Are there mini slings available</p>	<p style="text-align: right;">Page 56</p> <p>1 Q. Did you do any cadaver labs or 2 training for the Ethicon TVT-O?</p> <p>3 A. No, not that I recall.</p> <p>4 Q. Did you do the -- a cadaver lab 5 or training for TVT Secur?</p> <p>6 A. Not that I recall.</p> <p>7 Q. And did you do a cadaver lab or 8 any training for TVT-Exact?</p> <p>9 A. No, not that I recall.</p> <p>10 Q. Do you know if there's any 11 differences in the TVT-Exact as compared 12 to the TVT classic Retropubic?</p> <p>13 A. Yes, I know that there are 14 differences.</p> <p>15 Q. What are the differences?</p> <p>16 A. So, the needles are thinner, the 17 trocars to place the sling in, the -- 18 there's a plastic sheath that goes over 19 the TVT-Exact. So you have different ways 20 of implanting the sheath. TVT-Exact is 21 laser-cut, the mesh that I use, and the 22 traditional TVT that I had used was 23 mechanically-cut.</p> <p>24 Q. Did you use laser-cut TVT-R?</p>
<p style="text-align: right;">Page 55</p> <p>1 in the retropubic passage?</p> <p>2 A. Not right now, no.</p> <p>3 Q. Are there previously?</p> <p>4 A. I think TTV Secur was a little 5 more going in the same path as the 6 retropubic sling which would placed, but I 7 really didn't use that product.</p> <p>8 Q. What that --</p> <p>9 A. TTV Secur.</p> <p>10 Q. You did use it or you didn't use 11 it?</p> <p>12 A. I didn't use a TTV Secur.</p> <p>13 Q. You never did a TTV Secur?</p> <p>14 A. I may have done one, but it was 15 not a product that I used.</p> <p>16 Q. Let's go back.</p> <p>17 You trained on TTV Retropubic, 18 the classic TTV from Dr. Luente, correct?</p> <p>19 A. Correct.</p> <p>20 Q. Who did you train under with TTV 21 Obturator, or did you?</p> <p>22 A. Yeah, I did. I went to a 23 cadaver lab and that was an AMS-sponsored 24 cadaver lab.</p>	<p style="text-align: right;">Page 57</p> <p>1 A. Not that I recall.</p> <p>2 Q. You said there's sheathes with 3 TTV-Exact; is that correct?</p> <p>4 A. Yes.</p> <p>5 Q. Do you remember if there are 6 sheathes with TTV Retropubic?</p> <p>7 A. There's no sheath that goes on 8 a TTV Retropubic. It's sort of the needle 9 that screws into the device that you 10 would -- the TTV device that you would use 11 to implant the polypropylene and pass the 12 trocars.</p> <p>13 Q. Do you have an understanding of 14 why having a sheath with the TTV-Exact is 15 helpful?</p> <p>16 A. I think it's an easy way to pass 17 the sling. I've read in other reports 18 that people liked the TTV-Exact because 19 now they can do one cystoscopy.</p> <p>20 To be honest with you, I've 21 always done one cystoscopy. I just left 22 the trocar in from the traditional 23 retropubic and unscrewed it, went into the 24 other side and passed both in my slings.</p>

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<p>1 It passes very nicely and very easily. It 2 does not require a tremendous amount of 3 force to put the sling in. It's a nice 4 delivery device.</p> <p>5 Q. When you say it's easy to pass, 6 are you talking about the -- can you 7 describe what you mean?</p> <p>8 A. So, the force that I would need 9 in order to perforate through tissues.</p> <p>10 Q. So it minimizes maybe the 11 friction of the implanting device against 12 the tissue?</p> <p>13 A. You can say that, yes.</p> <p>14 Q. And conversely, without the 15 sheath, maybe there would be more 16 friction and more force required to 17 implant the device?</p> <p>18 A. So, I never tried with or 19 without the sheath with the needle 20 because there was no reason to go ahead 21 and do that. But it is a thinner needle 22 than the classic. So it required less 23 force and passed nicely and, in my mind, 24 maybe there was less chance of</p>	<p>1 MR. ROSENBLATT: Object to form. 2 A. Studies are -- all studies are 3 useful information to me, whether they're 4 good or bad, showing pluses or -- 5 positives or negatives.</p> <p>6 Q. If there are studies showing 7 decreased morbidity with a thinner needle, 8 would that guide your selection of which 9 device to use?</p> <p>10 A. So, if there's one needle that 11 has decreased morbidity and it's a safer 12 needle, quote/unquote, sure, I would like 13 to use the one that's safer.</p> <p>14 Q. When did you start using 15 TVT-Exact, if you remember?</p> <p>16 A. I don't remember. I apologize.</p> <p>17 Q. Was there a break where you 18 stopped using TVT Retropubic and switched 19 to TTVT-Exact that you remember?</p> <p>20 A. So, I think that the Boston 21 Scientific Advantage sling came out before 22 the TTVT-Exact. So, I did, I think, if I 23 recall correctly, that you would use the 24 Boston Scientific Advantage slings, and</p>
<p>1 perforation.</p> <p>2 Q. Do you know what the diameter of 3 the Exact trocars are?</p> <p>4 A. With -- I know there's a 5 difference with or without the sheath. 6 Somewhere around the 3 millimeter range, 7 but I don't have that committed to memory.</p> <p>8 Q. Do you know what the diameter of 9 the TTVT Retropubic classic was?</p> <p>10 A. Once again, not committed to 11 memory, but I think around 5 millimeters.</p> <p>12 Q. Do you have an understanding of 13 any clinical implications from having a 14 thinner trocar for the patient?</p> <p>15 A. I have not seen any clinical 16 implications of one versus the other that 17 one's better.</p> <p>18 Q. If there was some study showing 19 a difference, would you want to see those?</p> <p>20 A. I'm always willing to look at 21 studies, yes.</p> <p>22 Q. If there was studies that showed 23 decreased morbidity with a thinner needle, 24 would that be useful information for you?</p>	<p>1 then when TTVT-Exact came out, once again I 2 said I think they're interchangeable at 3 this point in time.</p> <p>4 Q. The first polypropylene sling 5 that you trained on was a TTVT, correct?</p> <p>6 A. Correct.</p> <p>7 Q. And then when would you have 8 trained on the Boston Scientific 9 Advantage?</p> <p>10 A. We're going back many years 11 here. I wish I could remember for you.</p> <p>12 Q. Was there a -- did you use the 13 TTVT Retropubic exclusively for a while?</p> <p>14 A. Yes.</p> <p>15 Q. And then at some point you 16 trained on Boston Scientific Advantage?</p> <p>17 A. So, no.</p> <p>18 So, first came the 19 Transobturator Monarch, right.</p> <p>20 Q. The AMS Monarch?</p> <p>21 A. Yes.</p> <p>22 Q. Let's go through the procession 23 of your history using slings. Initially you used TTVT</p>

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<p>1 Retropubic, correct?</p> <p>2 A. Correct.</p> <p>3 Q. You trained under Lucente in</p> <p>4 '98?</p> <p>5 A. Correct.</p> <p>6 Q. And then do you have a memory or</p> <p>7 recollection of what sling you used next?</p> <p>8 A. So, I always continued to use</p> <p>9 the retropubic. It's not that I shifted</p> <p>10 over one to the other. But then the</p> <p>11 transobturator sling came out and I also</p> <p>12 learned that technique and offered those</p> <p>13 slings to my patients as well.</p> <p>14 Q. So you went Ethicon TTV</p> <p>15 Retropubic and then AMS Monarch.</p> <p>16 Transobturator approach was</p> <p>17 available and then you added that to your</p> <p>18 surgical options to treat incontinence,</p> <p>19 correct?</p> <p>20 A. Correct.</p> <p>21 Q. And then what came after that?</p> <p>22 A. So then after that, I think the</p> <p>23 Boston Scientific Advantage sling came</p> <p>24 out. So I did transition some of my</p>	<p>1 Advantage was smaller needles?</p> <p>2 A. The Advantage Fit had a smaller</p> <p>3 needle. I use it interchangeably because</p> <p>4 they also had a thicker needle and that</p> <p>5 was the regular Advantage.</p> <p>6 Q. Doctor, do you treat</p> <p>7 complications that could arise from sling</p> <p>8 procedures?</p> <p>9 A. Yes.</p> <p>10 Q. Do you treat complications that</p> <p>11 arise from prolapse procedures?</p> <p>12 A. Yes.</p> <p>13 Q. Are you referred women who have</p> <p>14 had a mesh implanted from some other</p> <p>15 doctor?</p> <p>16 A. Sometimes.</p> <p>17 Q. And they're referred to you to</p> <p>18 treat complications from some other</p> <p>19 product that's been implanted that you did</p> <p>20 not implant; is that correct?</p> <p>21 A. Correct.</p> <p>22 Q. And similarly, you have an</p> <p>23 understanding that sometimes you might</p> <p>24 implant a product in a female patient and</p>
<p>1 retropubics over to the Boston Scientific</p> <p>2 Advantage.</p> <p>3 Q. And part of the reason for that</p> <p>4 was because you wanted to -- if you were</p> <p>5 using the Boston Scientific prolapse kit,</p> <p>6 you also wanted to use the Boston</p> <p>7 Scientific incontinence product; is that</p> <p>8 correct?</p> <p>9 A. Yes. And also if I was using</p> <p>10 anything for prolapse, because I would do</p> <p>11 transvaginal mesh procedures also, but if</p> <p>12 I was using -- I tried to stick with the</p> <p>13 same company, and I also liked the</p> <p>14 smaller, thinner needles.</p> <p>15 Q. And which product had the</p> <p>16 smaller, thinner needles?</p> <p>17 A. So, the Boston Scientific</p> <p>18 Advantage.</p> <p>19 Q. Do you have an understanding --</p> <p>20 A. You know what, let me clarify.</p> <p>21 You're probably right.</p> <p>22 There's an Advantage Fit and</p> <p>23 there's an Advantage.</p> <p>24 Q. And one of the advantages of the</p>	<p>1 she might seek treatment from another</p> <p>2 doctor, for whatever reason, for a</p> <p>3 complication, correct?</p> <p>4 A. Correct.</p> <p>5 Q. So it's hard to say what the</p> <p>6 experiences of all of your patients that</p> <p>7 you've implanted products in; is that</p> <p>8 correct?</p> <p>9 MR. ROSENBLATT: Object to form.</p> <p>10 A. Correct.</p> <p>11 However, I will tell you, and I</p> <p>12 mean, it's a small community in the urogyn</p> <p>13 field. I've been in the New York area for</p> <p>14 a long time, and I've actually asked some</p> <p>15 of my colleagues have they seen any of my</p> <p>16 complications and we do vice versa. As</p> <p>17 strange as it might seem, and I know all</p> <p>18 doctors say this, the majority of patients</p> <p>19 I know don't come back, but generally if</p> <p>20 there was a real significant complication,</p> <p>21 I think that I would hear about it.</p> <p>22 Q. Would you consider yourself a</p> <p>23 high-volume mesh implanter?</p> <p>24 A. It depends what you consider</p>

<p style="text-align: right;">Page 66</p> <p>1 high volume, but I probably do more of 2 these procedures than a lot of people 3 around in the New York area. 4 Q. And that probably affects your 5 complication rate probably. 6 The high volume helps you do it 7 safer; is that fair? 8 MR. ROSENBLATT: Object to form. 9 MR. BENTLEY: Let me rephrase it 10 a little bit. 11 Q. Would you agree that you as a 12 high-volume or having more frequent 13 opportunity to implant these mesh devices 14 gives you enable ability to implant them 15 safer and have a reduced complication 16 rate; is that fair? 17 A. I think my complication rate is 18 lower than what is quoted in the 19 literature. 20 However, generally when I 21 consent my patients, I use the 22 complication rate that's available in the 23 literature. 24 Q. And we'll get to the literature</p>	<p style="text-align: right;">Page 68</p> <p>1 see about five to ten women a year to 2 treat them for complications that arose 3 from a polypropylene sling for 4 incontinence; is that correct? 5 A. Well, so, let's clarify what we 6 mean by a complication, because if voiding 7 dysfunction is a complication, I'm seeing 8 more of those. If we're talking other 9 complications, more significant ones, 10 that's what I'm talking about the five to 11 ten. 12 Q. Let's go broad first. 13 Overall for all complications, 14 how many women do you think you see a year 15 that have complications that came from a 16 sling, a polypropylene sling that was 17 implanted to treat incontinence? 18 A. Overall probably about, I don't 19 know, 15, 20, some of them, including my 20 patients. 21 Q. And approximately five to ten of 22 those might have what you said I think is 23 serious complications? 24 A. Complications that may require</p>
<p style="text-align: right;">Page 67</p> <p>1 in a little bit. 2 Would you agree that the 3 literature shows that more high-volume 4 implanters have a lower rate of 5 complications? Is that fair? 6 A. Yeah, there's some data to show 7 that more experienced, quote/unquote, 8 surgeons may have a lower complication 9 rate. 10 Q. How many women do you think you 11 treat a year for complications that arise 12 from a sling that was implanted to treat 13 incontinence? 14 A. From a sling specifically? 15 Q. Yes. 16 A. Five to ten. 17 Q. And how many women do you think 18 you treat a year that have complications 19 that might have arisen from a prolapse 20 treatment that used a polypropylene mesh? 21 MR. ROSENBLATT: Object to form. 22 A. Repeat the question. 23 Q. Sure. Well, we talked about you 24 think you do five to ten -- you think you</p>	<p style="text-align: right;">Page 69</p> <p>1 more treatment than, let's say, a 2 medication or something like that. 3 Q. And what would the serious 4 complications include? 5 A. So, the serious complications 6 that I would commonly see, the most common 7 is mesh exposure. 8 Q. And what else? 9 A. Sometimes patients will have 10 some pain with intercourse associated with 11 the implant. Some patients can have 12 fistulas or mesh erosion into the bladder 13 or the urethra. 14 Q. The treatment can involve 15 surgery; is that correct? 16 A. Correct. 17 Q. And sometimes not surgery? 18 A. Correct. 19 Q. And sometimes multiple surgery, 20 correct? 21 A. With a sling, you usually can 22 get it on the first surgical procedure. 23 Q. Okay. You also see women that 24 have suffered complications after having a</p>

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<p>1 mesh product implanted to treat prolapse, 2 correct? 3 A. Yes. 4 Q. And approximately how many women 5 do you think you see on average per year 6 that are suffering from complications from 7 a prolapse treatment that involved a mesh? 8 A. About another -- about -- with 9 mesh, probably about five a year. 10 MR. ROSENBLATT: Greg, I will 11 give you a little leeway, but just try 12 to separate the prolapse questions for 13 the afternoon depo. 14 MR. BENTLEY: Okay. 15 BY MR. BENTLEY: 16 Q. We said approximately there's 17 five to ten serious complications women 18 per year per sling and approximately five 19 prolapse. 20 Is there another group that 21 you're seeing that have complications that 22 had both a prolapse and an incontinence? 23 Is that like a separate group? 24 A. No, that's probably all included</p>	<p>1 We can save that for later, if 2 you want. 3 Q. Of your five to six on average 4 revision surgeries per year, how many of 5 those do you think you're going in and 6 excising more mesh than just what's 7 exposed? 8 A. Well, I always take out a little 9 more mesh than is exposed in order to get 10 fresh edges so I don't have tension on my 11 repair. It really depends on why I'm 12 going in to take the mesh out. I will say 13 rarely do I feel if it's a prolapse mesh 14 do I need to take the entire mesh out. 15 And for slings, if it's the 16 sling is working and it's a simple little 17 exposure, then I would just try to keep 18 the sling intact and remove the small 19 piece that is exposed in order to get a 20 fresh edge to close it out. 21 Q. Some of the women that have had 22 a sling, they might have urinary 23 retention; is that correct? 24 A. That's correct.</p>
<p>1 in there. 2 Q. So you're probably doing 3 approximately 10 to 15 revision surgeries 4 per year or -- 5 A. No. 6 Q. How many revision surgeries do 7 you think you're doing per year? 8 A. Five, six revision surgeries a 9 year. 10 Q. And those revision surgeries are 11 usually for a mesh exposure? 12 A. Exposure or erosion into 13 bladder, urethra. 14 Q. Are you ever removing, going in 15 and removing the mesh, not just the 16 exposed mesh? 17 A. So, it depends on what the 18 problem was. I'll give you a for 19 instance, if you'd like. 20 In a patient who had a erosion 21 into the bladder from a Prolift mesh, 22 which is going to be later on in the 23 afternoon, I will take out a wider 24 dissection.</p>	<p>1 Q. And to surgically fix that, you 2 just go in and cut the mesh, correct? 3 A. Correct. 4 Q. It's called a release procedure 5 sometimes? 6 A. Yeah. So it's an incision into 7 the sling to release the sling. 8 Q. And no mesh -- 9 A. I had to do one on a urologist's 10 wife once. 11 Q. And no mesh is actually removed 12 in that procedure? 13 A. I don't remove mesh in that 14 procedure. 15 Q. When you're trimming or removing 16 mesh that's exposed, do you always send 17 that to a pathologist? 18 A. I always send it to my path 19 department. Generally they would just do 20 a gross on it. 21 However, there have been cases 22 where we've had to then send the mesh off 23 to plaintiff attorneys' path departments 24 and I happen to leave that to the path</p>

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<p>1 department.</p> <p>2 Q. And for fairness, it also gets</p> <p>3 examined by the defense pathologists.</p> <p>4 Do you know that?</p> <p>5 A. Yes, I know that.</p> <p>6 Q. Doctor, have you ever done any</p> <p>7 work as an expert in litigation before</p> <p>8 this case or these reports?</p> <p>9 A. I've done some malpractice work,</p> <p>10 but not -- this is my first product</p> <p>11 liability type of work.</p> <p>12 Q. And did you submit expert</p> <p>13 reports in those other cases?</p> <p>14 A. No.</p> <p>15 I've also actually way back</p> <p>16 when, I did some work for -- no reports,</p> <p>17 but I did review some charts for Caldera.</p> <p>18 Q. Have you ever examined a patient</p> <p>19 for what's called like a medical exam for</p> <p>20 litigation purposes?</p> <p>21 A. Yes.</p> <p>22 Q. When did you do that?</p> <p>23 A. I think they've been mostly for</p> <p>24 malpractice cases in the area when I was</p>	<p>1 that call me at this point in time.</p> <p>2 Q. So 95 percent of the work you do</p> <p>3 for litigation is for defendants?</p> <p>4 A. Correct.</p> <p>5 Q. Has your practice changed in</p> <p>6 that you see more patients now or less</p> <p>7 patients throughout your career? Or, can</p> <p>8 you describe that for me?</p> <p>9 A. So, as I've been getting older,</p> <p>10 I think the practice has changed a little,</p> <p>11 and I'm seeing more surgical patients as</p> <p>12 time goes on. That's about it. Surgery</p> <p>13 seems to be getting busier.</p> <p>14 Q. You were initially trained on</p> <p>15 the Burch, but today you don't really</p> <p>16 perform it very frequently; is that</p> <p>17 correct?</p> <p>18 A. Correct.</p> <p>19 Q. When do you think you, if you</p> <p>20 remember, when did you stop doing Burch</p> <p>21 probably?</p> <p>22 A. Probably somewhere in the late</p> <p>23 2000s.</p> <p>24 Q. Okay.</p>
<p style="text-align: center;">Page 75</p> <p>1 an expert on them. I am not sure if I --</p> <p>2 I have not done any examinations</p> <p>3 for any patients, that I'm aware of, that</p> <p>4 I remember, for this particular MDL.</p> <p>5 Q. But you've done some</p> <p>6 examinations for med-mal cases; is that</p> <p>7 correct?</p> <p>8 A. Correct.</p> <p>9 Q. Did you do those examinations on</p> <p>10 behalf of the defendants or the</p> <p>11 plaintiffs?</p> <p>12 A. Defendants.</p> <p>13 Q. Have you ever done any work on</p> <p>14 behalf of plaintiffs?</p> <p>15 A. So, I've worked on charts and</p> <p>16 reviewed charts for the plaintiffs.</p> <p>17 However, I never have gone to</p> <p>18 testify for plaintiffs.</p> <p>19 Q. Do you have any estimate of how</p> <p>20 often you do work for plaintiffs versus</p> <p>21 defendants?</p> <p>22 A. In the past, I did some more.</p> <p>23 Probably right now it's down to about five</p> <p>24 percent. There's only one or two people</p>	<p style="text-align: center;">Page 77</p> <p>1 A. I had a progression. I mean,</p> <p>2 so, the last patients that I did Burch on</p> <p>3 were as part of the cure study where in</p> <p>4 that case, they did recommend a</p> <p>5 prophylactic procedure in patients who</p> <p>6 were getting open abdominal</p> <p>7 sacrocolpopexies, those were Burch</p> <p>8 patients. As I transitioned away from</p> <p>9 open to robotic, we stopped doing the</p> <p>10 Burch procedure.</p> <p>11 Q. You still do the robotic</p> <p>12 procedures today, correct?</p> <p>13 A. I do the robotic procedure. So,</p> <p>14 we transitioned away from doing them open</p> <p>15 abdominal sacrocolpopexy, and I</p> <p>16 transitioned to more a more minimally</p> <p>17 invasive technique with laparoscopic</p> <p>18 robotic.</p> <p>19 Q. And that's for prolapse repair?</p> <p>20 A. That's for prolapse repair.</p> <p>21 Q. Doctor, have you ever done any</p> <p>22 work consulting for a medical device</p> <p>23 manufacturer?</p> <p>24 A. Yes.</p>

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<p>1 Q. Which companies have you worked 2 on behalf of?</p> <p>3 A. I'll try to remember them. Most 4 of them are in the CV.</p> <p>5 Q. If you want to look at your CV, 6 that's fine.</p> <p>7 A. I've worked with Boston 8 Scientific on developing products. I have 9 worked with Caldera, AMS.</p> <p>10 Q. What page are you on?</p> <p>11 A. Now I'm reading off memory, to 12 be honest with you.</p> <p>13 Q. Got you.</p> <p>14 A. In terms of devices, I have 15 consulted with Kimberly-Clark in terms of 16 an over-the-counter device for stress 17 incontinence.</p> <p>18 I have -- I'm trying to think if 19 there's anything else.</p> <p>20 Q. You're talking about consulting 21 for product design?</p> <p>22 A. So product design, yes, I 23 consulted with Boston Scientific on 24 product design, as well as Caldera, and as</p>	<p>1 know if I ever -- I may have and I may not 2 have precepted for Caldera. That I don't 3 really remember if anyone came to the OR 4 for that or not, to be honest with you.</p> <p>5 Q. For Caldera?</p> <p>6 A. Yeah. And I precepted for 7 Boston Scientific as well.</p> <p>8 Q. If you could look at page 6 of 9 your CV, which is marked as 3.</p> <p>10 A. Yes.</p> <p>11 Q. There's a listing of your 12 teaching experience; is that correct?</p> <p>13 A. Yes.</p> <p>14 Q. And this has, for example in 15 August 2003 you did an AMS monarch cadaver 16 lab where you were lecturing an 17 instructor.</p> <p>18 Do you see that?</p> <p>19 A. Yes.</p> <p>20 Q. And then there's an AMS below 21 that, then a Boston Scientific.</p> <p>22 Does this reflect your teaching 23 on behalf of medical device companies?</p> <p>24 A. Yes.</p>
<p>1 well as probably with AMS Astora.</p> <p>2 Q. And then another -- I notice on 3 your CV it says you've taught or precepted 4 on behalf of AMS, correct?</p> <p>5 A. Correct.</p> <p>6 Q. And you've also taught on behalf 7 of Boston Scientific?</p> <p>8 A. Correct.</p> <p>9 Q. Have you talked on behalf of any 10 other companies?</p> <p>11 MR. BENTLEY: I'm sorry, that 12 was a horrible question.</p> <p>13 Q. Have you taught on behalf of any 14 other medical device manufacturers?</p> <p>15 A. In terms of cadaver labs, no. 16 These are the two that I recall that I've 17 done, the two companies.</p> <p>18 Q. Other than cadaver labs, have 19 you taught on behalf of any other medical 20 device manufacturer?</p> <p>21 A. So, I was a preceptor for J&J in 22 the early 2000s.</p> <p>23 Q. For what product?</p> <p>24 A. For TVT. And I also -- I don't</p>	<p>1 Q. And you testified that you 2 taught on behalf of J&J in the early 3 2000s; is that correct?</p> <p>4 A. Yeah, but I don't think I ever 5 did a, like, a cadaver lab or anything 6 like that for them. At least not that I 7 recall. Some of this I'd have to put 8 together and think back.</p> <p>9 Q. So this is only teaching 10 experience specific to cadaver labs; is 11 that your testimony?</p> <p>12 A. Yes.</p> <p>13 Q. Why are these other entries on 14 here that don't say "cadaver lab"?</p> <p>15 A. Which one?</p> <p>16 Q. For example, April 2008 female 17 urology and urogynecology symposium 18 lecture, that's not a cadaver lab, is it?</p> <p>19 A. No. So where it says, like, 20 October 2003 AMS Monarch cadaver lab. 21 Usually when I did a cadaver lab, I tried 22 to write it down.</p> <p>23 Q. Is there any reason why you 24 don't include your other teaching</p>

<p style="text-align: right;">Page 82</p> <p>1 employment on here from J&J?</p> <p>2 A. No. This is for the medical</p> <p>3 school. So they want to know what I'm</p> <p>4 treating and teaching, you know, in big</p> <p>5 groups. They're not really interested in</p> <p>6 a doctor coming and watching and seeing</p> <p>7 me.</p> <p>8 Q. When you say that you precepted</p> <p>9 for J&J in the early 2000s, approximately</p> <p>10 how many years did you teach on behalf of</p> <p>11 J&J for?</p> <p>12 A. I don't think it was very long,</p> <p>13 and I don't think it was a lot of docs.</p> <p>14 It may have been for probably two, three</p> <p>15 years only.</p> <p>16 Q. Did you get paid?</p> <p>17 A. Yes.</p> <p>18 Q. Are there other teaching</p> <p>19 activities you've done on behalf of</p> <p>20 medical device manufacturers that are not</p> <p>21 included on here in addition to the J&J</p> <p>22 work?</p> <p>23 A. For cadaver labs, I tried to</p> <p>24 write them down. If I was invited to a</p>	<p style="text-align: right;">Page 84</p> <p>1 recent.</p> <p>2 Q. So if you were going to update</p> <p>3 this today, would you add being a</p> <p>4 consultant for Ethicon or J&J to your CV?</p> <p>5 A. I guess I would add it, yes, at</p> <p>6 this point in time. It's mostly for</p> <p>7 precepting. Once again, I didn't do</p> <p>8 any -- I didn't do any cadaver labs or</p> <p>9 whatnot, but I could add that, yes.</p> <p>10 Q. So it's your testimony today</p> <p>11 that the only work you've done for J&J</p> <p>12 other than this expert work in the MDL is</p> <p>13 for preceptorship?</p> <p>14 A. So, I did that and I may have</p> <p>15 gone to some meetings that they have</p> <p>16 sponsored and I may have gotten paid for</p> <p>17 that. I don't recall what they were.</p> <p>18 Q. So you may have spoken on behalf</p> <p>19 of --</p> <p>20 MR. ROSENBLATT: I just want to</p> <p>21 object to form. You're asking him</p> <p>22 about the past 20 years or so.</p> <p>23 MR. BENTLEY: Right.</p>
<p style="text-align: right;">Page 83</p> <p>1 meeting or an advisory, I may have missed</p> <p>2 that early on in my career, because to be</p> <p>3 honest with you, I just didn't record all</p> <p>4 that stuff back then.</p> <p>5 Q. But ultimately you started</p> <p>6 including that information on your resume?</p> <p>7 A. Correct.</p> <p>8 Q. And where are those non-cadaver</p> <p>9 lab stuff that later in your career you</p> <p>10 started including on here?</p> <p>11 A. So, if I did an advisory board,</p> <p>12 that would be on here.</p> <p>13 Let's see what page that's on.</p> <p>14 So, starting on page 2 Other</p> <p>15 Professional Positions. I wrote that I</p> <p>16 was a consultant for AMS. And once again,</p> <p>17 it may have been earlier, but this form</p> <p>18 for the medical school came out around, I</p> <p>19 guess, somewhere several years ago when I</p> <p>20 was up for associate professor, so five</p> <p>21 years ago or somewhere. So that's when I</p> <p>22 started really recording. Some of them I</p> <p>23 have to go back to memory. But right now</p> <p>24 that's what I have and that's what's</p>	<p style="text-align: right;">Page 85</p> <p>1 BY MR. BENTLEY:</p> <p>2 Q. Your CV doesn't reflect any</p> <p>3 employment for J&J whatsoever, does it?</p> <p>4 A. It doesn't -- I was never</p> <p>5 employed by J&J.</p> <p>6 Q. You got paid by J&J, didn't you?</p> <p>7 A. Correct.</p> <p>8 Q. And your CV doesn't reflect any</p> <p>9 of those payments or any of that work,</p> <p>10 correct?</p> <p>11 A. Yes. It's not because I'm</p> <p>12 trying to hide anything like that. Once</p> <p>13 again, it's going back a long time. I</p> <p>14 totally forgot about the stuff that I did</p> <p>15 for J&J when I put this together. I</p> <p>16 didn't include any of the other stuff that</p> <p>17 I got paid for back then from Boston</p> <p>18 Scientific or from AMS. Once again, it</p> <p>19 wasn't an academic thing, so I didn't put</p> <p>20 it on my academic CV.</p> <p>21 Today we have -- there's more</p> <p>22 disclosure going on. I fill out all my</p> <p>23 conflict of interests and it's disclosed</p> <p>24 on there, and you can go on the Web site</p>

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<p>1 for Medicare and see it as well. 2 Q. I mean, you would agree that 3 conflict disclosure is important 4 information, wouldn't you? 5 A. I agree that's important, and I 6 usually adhere to the requirements of the 7 time. 8 Q. So, in addition to the J&J work 9 that you did in the early 2000s, there's 10 also Boston Scientific and AMS work that's 11 not on this resume? 12 A. There may be. But once again, 13 some of the cadaver labs are on the CV. 14 So work that I did for them is there. 15 If I did any consulting on 16 device development or on any kind of 17 improvements to any of their devices that 18 I would have consulted on, I probably 19 didn't include that on here on this one. 20 Q. You didn't include on here on 21 this one, you're talking about this CV? 22 A. On my CV, I probably would not 23 have included the early 2000 stuff. 24 Once again, academically, it</p>	<p>1 with them if they were bringing in -- out 2 a new product, they would show it to me. 3 I would maybe do a cadaver lab with them. 4 I would give my advice on new product 5 development as well as products that they 6 have in development. 7 Q. And that information is not 8 listed on your CV? 9 A. Well, it is. Consultant. I 10 started putting, in 2012, I started 11 writing down when I was a consultant and 12 recording that kind of stuff. 13 Q. So that information just isn't 14 recorded prior to 2012; is that fair? 15 A. Yes. 16 Q. And additionally, you did some, 17 it looks like, studies with some of these 18 companies; is that correct? 19 A. Correct. 20 Q. It says "Contracts, grants and 21 sponsor research" on page 9. 22 Do you see that? 23 A. Okay. 24 Q. And is this a list of the</p>
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<p>1 really wasn't pertinent at that point in 2 time, so I didn't include it. 3 Q. That was in the early 2000s? 4 A. Correct. 5 Q. At what point would you have 6 changed and decided that information would 7 be pertinent to include on your CV? 8 A. So, when I started doing this 9 and really updating this on an ongoing 10 basis when I was up for associate 11 professor, that's probably what I started. 12 And let's see when I was up for 13 an associate. So, I was approved for an 14 associate professor in 2013. I probably 15 started working on this format of this CV 16 about a year earlier in 2012. 17 Q. So, you did some teaching on 18 behalf of, according to your CV, you did 19 some teaching on behalf of Boston 20 Scientific and AMS. 21 Additionally, did you do some 22 other work for those companies? 23 A. Yeah. I would consult with them 24 on device development. I would consult</p>	<p>1 studies you worked on? 2 A. Yes. Not all the studies. I 3 got some clarification on what studies 4 they really wanted on here, but these were 5 some of the major studies and anything 6 that would have a possibility with a grant 7 or grant money that was obtained, but we 8 do a lot of studies where in the office 9 where we don't get money for or we don't 10 get grants for and those generally aren't 11 included in here unless it's a large 12 multicenter study. 13 Q. And the grant money doesn't go 14 to you; it goes to your hospital, right? 15 A. Does not go to me. 16 Q. But you included on here studies 17 that received grant money that went to 18 your hospital; is that fair? 19 A. Yes. 20 Q. Is this a complete list of the 21 work you've done or the studies you've 22 done that received grant money to your 23 hospital? 24 A. That I'm aware of, yes.</p>

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<p>1 Q. Are there studies that you might 2 have forgotten about or didn't include? 3 A. Yes, there's always that 4 possibility. Once again, I started doing 5 this format around 2012. So before that, 6 some of that may have been from memory and 7 just having to go back to some of the open 8 payroll, whatever accounts there were in 9 the hospital to find out from them if they 10 were -- if grant money was obtained. 11 Q. So you went back to see if grant 12 money was obtained, you included those 13 studies on your CV? Is that it? 14 A. I tried to, yes. 15 Q. And looking at your studies, it 16 looks like in 2003 you started a study 17 with the AMS Monarch. Do you see that? 18 You were an investigator? 19 A. Which one? 20 Q. The second. 21 A. On page 9? 22 Q. Yes. 23 A. Yes. 24 Q. So that's a study that you did</p>	<p>1 long time. I don't really remember and if 2 we enrolled a patient or not. 3 Q. I'm having a hard time. 4 How do we know what you worked 5 on in the 2000s? Is there just no way to 6 know at this point? 7 A. Whatever's here is what I 8 remember at this point in time. Whatever 9 I thought was pertinent to in order to for 10 academically, that's why I put it on 11 there. And there may have been a patient 12 or two in the perigee one, I just don't 13 recall. 14 Q. Then on the next page the 15 complete entry on the top is 2006-2008. 16 Do you see that's a Boston 17 Scientific study you worked on? 18 A. Yes. 19 Q. And then I guess -- 20 A. See, I started to get better. 21 Q. You get better at what? 22 A. I started to get better at 23 recording the stuff and remembering it 24 because it was just available to me.</p>
<p style="text-align: center;">Page 91</p> <p>1 of the AMS Monarch that was from 2003 to 2 2005 \$29,000 disclosed, correct? 3 A. Correct. 4 Q. So at least in -- some time in 5 the early 2000s, you were including 6 studies on here that you received money 7 for, correct? 8 A. Correct. 9 Q. Then two down from there there's 10 another AMS study that you participated 11 in? 12 Do you see that? 13 A. Yes. 14 Q. And that one was started in 2005 15 and ended in 2008; is that correct? 16 A. Yes. So once again, this is 17 going back eight years. I'm going to 18 assume if I didn't put money down is we 19 probably didn't enroll patients in or the 20 study changed or something like that. 21 Q. But if you enrolled patients, 22 you would have included on here? 23 A. I likely would have. 24 Once again, this is going back a</p>	<p style="text-align: center;">Page 93</p> <p>1 Q. What was available to you? 2 A. No, the information to put down. 3 Q. But the information was 4 available to you in the early 2000s also, 5 wasn't it? 6 A. Yes, but I didn't put this CV 7 together then. 8 Q. You didn't keep a CV from the 9 beginning of your career? 10 A. I did. Once again, not putting 11 down everything like I needed to put down 12 in this CV. 13 Q. And it's your testimony that you 14 started making a complete CV around 2013 15 when you were up for assistant 16 professorship? 17 MR. ROSENBLATT: Object to form, 18 characterization. 19 A. So, I always had a CV. 20 When I needed to put this form 21 together, there was more information that 22 was requested than I probably had on my 23 old one, and that's why I needed to do 24 some going back. Like I didn't keep a</p>

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<p>1 record of every single grand rounds that I 2 did. I was doing a lot back then. I had 3 to go back and try to figure out which 4 ones I gave, where they were and whatnot. 5 Q. Today would you like to go back 6 and update this CV and add some work for 7 any companies?</p> <p>8 A. I mean, I can add the consultant 9 for J&J. Once again, that was in the 10 early 2000s. I don't think academically 11 they would care at that point in time 12 going back, but sure, I'd put it down. 13 It's not a problem.</p> <p>14 Q. Today you'd like to do that?</p> <p>15 MR. ROSENBLATT: Object to form. 16 You don't have to do anything.</p> <p>17 BY MR. BENTLEY:</p> <p>18 Q. I'm not asking you what you have 19 to do.</p> <p>20 If you had the opportunity to 21 update this CV, would you like to add --</p> <p>22 A. I probably wouldn't formally 23 update it at this point in time. I would 24 just leave it at this for the academic</p>	<p>1 short break. 2 Are you ready to go? 3 A. Yes. 4 Q. Before the break, we were 5 discussing that you may have worked as a 6 preceptor for Ethicon in the early 2000s. 7 Do you remember that? 8 A. I didn't say "may." I did work 9 as a preceptor for them.</p> <p>10 MR. BENTLEY: I'm going to hand 11 you what's being marked as Exhibit 21. 12 (Exhibit 21, e-mail chain ending 13 August 15, 2001, Bates No. 14 ETH.MESH.25126573 through 15 ETH.MESH.25126575, was marked for 16 identification, as of this date.)</p> <p>17 THE WITNESS: I just want to 18 comment that on the grants, we 19 discussed this beforehand, but none of 20 this grant money went to me. It all 21 went to my hospital.</p> <p>22 MR. BENTLEY: Appreciate that, 23 thank you.</p>
<p>1 Page 95</p> <p>2 stuff 'cause once again, that was 14 years 3 ago. If somebody wanted to know it, I 4 have no problem with disclosing it.</p> <p>5 Q. What was 14 years ago?</p> <p>6 A. When I did the consulting work 7 for J&J.</p> <p>8 Q. And today it's 2017.</p> <p>9 Fourteen years ago would have been?</p> <p>10 A. 2003, '4. So 13, 14 years ago.</p> <p>11 Q. And your testimony today is 12 that's when your consulting with Ethicon 13 stopped?</p> <p>14 A. That's what I recall. I don't 15 remember, once again. I don't have the 16 1099s from back then. I don't have 17 information from back then or any tax 18 information.</p> <p>19 MR. BENTLEY: Take a break?</p> <p>20 MR. ROSENBLATT: Sure. 21 (Recess taken from 10:06 a.m. to 22 10:21 a.m.)</p> <p>23 BY MR. BENTLEY:</p> <p>24 Q. Doctor, we're back from the</p>	<p>1 BY MR. BENTLEY: 2 Q. So, Exhibit 21 is a e-mail, 3 Bates on the bottom right which we refer 4 to to identify pages, it's 5 ETH.MESH.25126573. 6 Do you see that? 7 A. Yes. 8 Q. And this is an e-mail from Greg 9 Slusser on August 2001. 10 Do you see that? 11 A. Okay. 12 Q. And do you know who Greg Slusser 13 is? 14 A. I mean, he works for Ethicon. I 15 can see that. 16 Do I remember him? I don't -- 17 Q. It was a while ago. 18 A. Yeah. 19 Q. And you see the subject line of 20 the e-mail is "Preceptor summit 21 information"? 22 A. Correct. 23 Q. Then it's an e-mail string, you 24 can see further down is the earlier</p>

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<p>1 message and the original e-mail from Brian 2 Luscombe on August 14th, 2001. 3 Do you see that? 4 A. Yes. 5 Q. And he starts the e-mail: 6 "Attached is the information recently 7 mailed to all preceptors with regard to 8 the TVT preceptor summit meeting." 9 Do you see that? 10 A. Yes. 11 Q. Then on the next page on Bates 12 the last three is '574, do you see there's 13 a list of people that have confirmed their 14 attendance? 15 A. Yes. 16 Q. And your name, Harvey Winkler, 17 is at the bottom of that first list. 18 Do you see that? 19 A. Yes, it is. 20 Q. And that's consistent with your 21 testimony today that in the early 2000s, 22 you were preceptor for J&J or Ethicon, 23 correct? 24 A. Yes.</p>	<p>1 Do you see that? 2 A. Yes, I do. 3 Q. And this is in 2005 you're 4 speaking on behalf of Ethicon, a J&J 5 subsidiary, correct? 6 A. I don't know if I would call it 7 speaking on behalf of them. If I remember 8 correctly, this was a lecture on the 9 pelvic floor incontinence and this was 10 about using mesh on the pelvic floor. 11 Q. And you were being paid, 12 correct? 13 A. I was being paid, yes. 14 Q. Then I'm going to hand you 15 what's being marked as exhibit -- 16 A. And I think this is on my CV, by 17 the way. 18 Q. Could you point me to what page 19 of Exhibit 3 it lists that you worked on 20 behalf of J&J and you spoke -- 21 A. It's page 7 of my CV, 22 Cedars-Sinai Medical Center. 23 Q. On page 7 of Exhibit 3, which is 24 your CV, you spoke at Cedars-Sinai Medical</p>
<p>1 Q. Then I'm going to hand you 2 what's being marked as Exhibit 23. 3 (Exhibit Winkler 23, e-mail 4 chain ending February 7, 2005, Bates 5 No. ETH.MESH.25042561 through 6 ETH.MESH.25042562, was marked for 7 identification, as of this date.) 8 BY MR. BENTLEY: 9 Q. This is another e-mail that was 10 produced to us by Ethicon, and its Bates 11 is 25042561. 12 Do you see that? 13 A. Yes. 14 Q. And this is an e-mail from 15 February 7th, 2005 from Donna Abely. 16 Do you see that? 17 A. Mm-hm. 18 Q. And she starts: "Thanks, Jim. 19 Dr. Hall is working on gathering all of 20 this information. She just called to me 21 inform, however, that because Dr. Winkler, 22 the speaker, is traveling from the east 23 coast he's requesting a two-day 24 honorarium."</p>	<p>1 Center; is that correct? 2 A. That's what this was, correct. 3 Q. And it says "guest lecture," 4 correct? 5 A. Yes. 6 Q. And nowhere on your CV does it 7 say you got paid by Ethicon, correct? 8 A. There's nowhere on this CV that 9 you need to write who your honorarium came 10 from. 11 MR. BENTLEY: I'm going to move 12 to strike. 13 MR. ROSENBLATT: Greg, let him 14 answer the question. Then you can 15 move to strike. 16 Q. Finish the answer, please. 17 A. It's not required to put on your 18 CV where the honorarium comes from. 19 Q. Do you remember what my question 20 was, Doctor? 21 A. No. 22 Q. Nowhere on this CV does it state 23 that you were paid by Ethicon to speak at 24 Cedars-Sinai, does it?</p>

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<p>1 MR. ROSENBLATT: And you can 2 answer the question and provide the 3 context that you think is necessary. 4 A. Once again, I wasn't paid to 5 speak there. They invited me. It was an 6 honorarium to compensate me for my out of 7 time out of the office. 8 Q. My question is very precise, and 9 then if you need to explain afterward, 10 that's totally fine. 11 But my question is nowhere on 12 your CV does it say that you got paid to 13 speak at Cedars-Sinai by Ethicon, as we 14 just saw in that e-mail, does it? 15 MR. ROSENBLATT: Object to form; 16 asked and answered. 17 A. It does not say that on my CV. 18 Q. Doctor, I'm going to hand you 19 what's been marked as Exhibit 24. 20 (Exhibit Winkler 24, Power Point 21 presentation Eastern Region Region of 22 the Year by Paul Parisi, April 24, 23 2011, was marked for identification, 24 as of this date.)</p>	<p>1 opinion leader back in 2005, or who 2 considered me what. 3 Q. But today you consider yourself 4 a key opinion leader for Ethicon? 5 MR. ROSENBLATT: Object to form. 6 A. I consider myself knowledgeable 7 in the field. Am I -- if you want to 8 consider me a key opinion leader, yes, 9 some people may, some people may not. 10 Q. If you turn the page on page 4 11 of this Power Point, there's a little 4 on 12 the bottom left. 13 Do you see? 14 A. Mm-hm. 15 Q. Yes? 16 A. Yes, I do. I'm sorry. 17 Q. That's okay. 18 Then on the bottom right -- 19 well, on the top left it says "KOL." 20 Do you see that top heading? 21 A. Yes. 22 Q. Then on the bottom right it says 23 "Metro," and your name is listed under 24 "Metro."</p>
<p style="text-align: center;">Page 103</p> <p>1 BY MR. BENTLEY: 2 Q. This is a Power Point titled: 3 "Eastern Region Region of the Year," dated 4 April 24, 2011. 5 Do you see that? 6 A. Yes. 7 Q. And then on the bottom left 8 corner it says: "Professional education." 9 Do you see that? 10 A. Yes, I do. 11 Q. If you turn the page it says: 12 "Keys to winning," on the second page. 13 Do you see that? 14 A. Yes. 15 Q. In the bottom right corner it 16 says "KOLs." 17 Do you know what KOLs are? 18 A. Key opinion leader, yes. 19 Q. Were you a key opinion leader 20 for Ethicon? 21 MR. ROSENBLATT: Object to form. 22 Q. If you know. 23 A. I'm a key opinion leader today. 24 I did not know if I was a key</p>	<p style="text-align: center;">Page 105</p> <p>1 Do you see that? 2 A. Yes, I do. 3 Q. So 2011, at least according to 4 this Power Point, you're considered a key 5 opinion leader for professional education 6 for Ethicon. 7 Is that fair? 8 A. Yes. 9 Q. Today as we sit here and seeing 10 these documents, would you like to add 11 some of this information to your CV? 12 A. I don't think that this is 13 pertinent to my CV. 14 If somebody asks me to disclose 15 any of this information, I have no problem 16 with disclosing it. 17 Q. So you wouldn't want to add any 18 of this information to your CV? 19 MR. ROSENBLATT: Objection. 20 A. I don't know if I would add it 21 or not to my CV. Once again, being a 22 consultant, I can put on. That's not a 23 problem. Whether or not it's going to 24 make a difference for academic promotion,</p>

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<p>1 I don't think it will and that's why I 2 maintain the bulk of my CV. 3 But I don't think I was a 4 consultant for Ethicon in 2011. I may 5 have been considered a key opinion leader, 6 but I don't recall being a consultant for 7 them in that year.</p> <p>8 You probably have access to that 9 information easier than I do.</p> <p>10 Q. Just so I understand, for 11 purposes, for academic purposes, you don't 12 feel that you need to update your CV? Is 13 that your testimony?</p> <p>14 MR. ROSENBLATT: Object to form; 15 mischaracterization.</p> <p>16 A. I didn't say that. I said I 17 would think about it, if adding them as a 18 consultant to the CV.</p> <p>19 Once again, I'm not going to do 20 it when I go back right away, but I don't 21 have a problem adding that to my CV and 22 disclosing that to anybody.</p> <p>23 Q. If you end up testifying at 24 trial before the jury, would you want to</p>	<p>1 the work that you've billed on -- does 2 this Exhibit 20 reflect the work that 3 you've billed to prepare your TTV report? 4 A. Yes. 5 Q. And the description of your work 6 includes review of articles, research and 7 writing report; is that correct? 8 A. Correct. 9 Q. And is this all the time that 10 you put into those activities, reviewing, 11 researching and writing your report? 12 A. I put some more activities in 13 together, but I've been so busy, I have 14 not had a time to add any of that stuff up 15 yet. 16 Q. So as we sit here today, you 17 have more time that needs to be billed 18 that you know of? 19 MR. ROSENBLATT: Object to form. 20 You're asking about what went 21 into his report, right? 22 MR. BENTLEY: Right. Thank you. 23 BY MR. BENTLEY: 24 Q. Do you have any additional time</p>
<p>1 update your CV before beginning the trial 2 to include this work for Ethicon?</p> <p>3 MR. ROSENBLATT: Object to form. 4 Which consulting work are you 5 referring to?</p> <p>6 BY MR. BENTLEY:</p> <p>7 Q. You can answer the question, if 8 you understand.</p> <p>9 A. So, I would consider adding my 10 consulting work that I did for J&J in the 11 early 2000s. Thank you for reminding me.</p> <p>12 Q. Appreciate it.</p> <p>13 Doctor, I just handed you an 14 exhibit, which is I believe your invoice 15 from the TTV report.</p> <p>16 What number did I put on that 17 bottom right?</p> <p>18 A. 20.</p> <p>19 (Exhibit Winkler 20, Invoice No. 20 1011 of Harvey Winkler, M.D., dated 21 January 17, 2017, was marked for 22 identification, as of this date.)</p> <p>23 BY MR. BENTLEY:</p> <p>24 Q. And does this Exhibit 20 reflect</p>	<p>1 to bill for the preparation of your report 2 that you know of today? 3 A. I may have, yes. 4 Once again, I don't know the 5 hours or the numbers 'cause I had sent 6 this report in January 17th. Today is 7 March -- what is today, March 12? 8 Q. Right. 9 A. I signed off on this report on 10 February 5th. So I probably did more work 11 in between. 12 Q. In between? 13 A. In between January -- 14 Q. 17? 15 A. Well, this is up to January 3rd, 16 right. 17 Q. I got you. 18 A. I just sent out the bill on the 19 17th before I went away. 20 So, there may well be more time 21 that I have spent on, and likely there is. 22 Q. Do you have an estimate of how 23 much more time after January 3rd you're 24 going to bill for --</p>

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<p>1 A. I don't recall. I apologize.</p> <p>2 MR. ROSENBLATT: And Greg, I'm</p> <p>3 happy to produce the information when</p> <p>4 we get it.</p> <p>5 THE WITNESS: Yeah, not a</p> <p>6 problem.</p> <p>7 BY MR. BENTLEY:</p> <p>8 Q. Your hourly rate for preparing</p> <p>9 report and reviewing material was \$650 an</p> <p>10 hour, correct?</p> <p>11 A. Correct.</p> <p>12 It's expensive to live in New</p> <p>13 York.</p> <p>14 Q. That's true.</p> <p>15 Is that also your rate for this</p> <p>16 deposition today?</p> <p>17 A. So, my deposition -- I didn't</p> <p>18 really discuss this, to be honest with</p> <p>19 you. I thought this was going to be a</p> <p>20 seven-hour deposition, and then you guys</p> <p>21 increased it to a nine-hour deposition.</p> <p>22 So, yes, it's either -- it will</p> <p>23 be around the 650 an hour. My deposition</p> <p>24 daily rate is 7,000. I was going to</p>	<p>1 (Discussion held off the record.)</p> <p>2 BY MR. BENTLEY:</p> <p>3 Q. Earlier we were discussing your</p> <p>4 use of different polypropylene slings.</p> <p>5 Do you remember that?</p> <p>6 A. Yes.</p> <p>7 Q. And you testified that you used</p> <p>8 TVT classic.</p> <p>9 A. Okay.</p> <p>10 Q. I believe you said you used the</p> <p>11 machine-cut TVT classic; is that correct?</p> <p>12 A. Yes.</p> <p>13 Q. And then today you use</p> <p>14 TVT-Exact, correct?</p> <p>15 A. Correct.</p> <p>16 Q. And TVT Exact is laser-cut,</p> <p>17 correct?</p> <p>18 A. Correct.</p> <p>19 Q. I thought you said you never</p> <p>20 used a laser-cut TVT-R; is that correct?</p> <p>21 A. I don't think that I have.</p> <p>22 Q. And so on page 7, that last</p> <p>23 paragraph, the third line down you say:</p> <p>24 "I have implanted traditional TVT</p>
<p>1 figure out what we were going to bill for</p> <p>2 today.</p> <p>3 Q. Charge him more.</p> <p>4 A. I don't know about charge him</p> <p>5 more. I wouldn't charge more than the 650</p> <p>6 an hour, but we will be here for 12 hour --</p> <p>7 how long are you going to keep me here?</p> <p>8 Q. We'll see.</p> <p>9 Is your daily rate for trial the</p> <p>10 same?</p> <p>11 A. It's 8,000. It's in my CV.</p> <p>12 Trials don't go past nine</p> <p>13 o'clock at night, right?</p> <p>14 Q. No comment.</p> <p>15 So, let's look at your report.</p> <p>16 A. Okay. The TVT report, to be</p> <p>17 exact?</p> <p>18 Q. TVT report we've entered as</p> <p>19 Exhibit 2, I believe.</p> <p>20 A. Okay, I'm ready.</p> <p>21 Q. If you could turn to page 7 of</p> <p>22 your report, please.</p> <p>23 THE WITNESS: Could we go off</p> <p>24 the record for a second?</p>	<p>1 mechanically-cut and laser-cut."</p> <p>2 Do you see that?</p> <p>3 A. Yes.</p> <p>4 Okay. So, what I mean to</p> <p>5 clarify -- so, doesn't matter if you call</p> <p>6 it -- I call TVT classic or</p> <p>7 mechanically-cut, laser-cut. Traditional</p> <p>8 cut meant general TVT, not traditional</p> <p>9 mechanical-cut. So I've done both.</p> <p>10 Do you understand?</p> <p>11 Q. I don't.</p> <p>12 So, before you switched to</p> <p>13 TVT-Exact, you were using TVT-R or TVT</p> <p>14 classic, correct?</p> <p>15 A. Correct.</p> <p>16 Q. And you testified today that you</p> <p>17 used mechanically-cut TVT-R, correct?</p> <p>18 A. Correct.</p> <p>19 Q. Which you no longer use today,</p> <p>20 correct?</p> <p>21 A. Correct.</p> <p>22 Q. But your report says you used</p> <p>23 TVT, mechanically-cut and laser-cut.</p> <p>24 That's what that says, right?</p>

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<p>1 A. It does.</p> <p>2 Q. Can you explain that?</p> <p>3 A. I mean, what we're calling</p> <p>4 traditional, classic, I just meant</p> <p>5 traditional TVT as TVT-type slings and</p> <p>6 then I separate it into I've done</p> <p>7 mechanically-cut TVT slings and laser-cut</p> <p>8 TVT slings.</p> <p>9 Q. Just so I understand, the</p> <p>10 laser-cut retropubic device made by</p> <p>11 Ethicon that you use is TVT Exact?</p> <p>12 A. Correct.</p> <p>13 Q. And did you use TVT Retropubic</p> <p>14 laser-cut?</p> <p>15 A. Not that I recall.</p> <p>16 Q. Okay. Doctor, on page 7 you</p> <p>17 have some estimates of how many procedures</p> <p>18 you've done.</p> <p>19 Do you see that?</p> <p>20 A. Yes.</p> <p>21 Q. How did you come to those</p> <p>22 numbers?</p> <p>23 A. These are very gross estimates.</p> <p>24 I don't have case logs and whatnot. So</p>	<p>1 literature apart, or aside, in your</p> <p>2 estimation, do you have any idea of how</p> <p>3 many of the 3,000 slings you've implanted</p> <p>4 that those women had any type of</p> <p>5 complication?</p> <p>6 A. Any type of complication, if</p> <p>7 we're talking about exposure, erosion,</p> <p>8 going back I would say somewhere between,</p> <p>9 I don't know, two, three percent.</p> <p>10 Really this is gross 'cause once</p> <p>11 again I have not gone back.</p> <p>12 Q. I'm not asking you to guess.</p> <p>13 A. Yeah, it's a guess.</p> <p>14 Q. And then likewise, you don't</p> <p>15 have an estimate of how many of those</p> <p>16 3,000 slings you implanted, you don't have</p> <p>17 a reasonable or accurate estimate of how</p> <p>18 many had an erosion, correct?</p> <p>19 MR. ROSENBLATT: Object to form.</p> <p>20 MR. BENTLEY: Let me rephrase</p> <p>21 it.</p> <p>22 BY MR. BENTLEY:</p> <p>23 Q. Do you have any reliable way of</p> <p>24 calculating what percent of your 3,000</p>
<p style="text-align: center;">Page 115</p> <p>1 these are just trying to think back of how</p> <p>2 many I do a year and how much I did in</p> <p>3 fellowship.</p> <p>4 It's very, very gross.</p> <p>5 Q. You didn't go back and review</p> <p>6 any operative reports or anything like</p> <p>7 that?</p> <p>8 A. No, no.</p> <p>9 Q. Do you have an estimate of how</p> <p>10 many of the 3,000 midurethral slings</p> <p>11 you've implanted, how many of those women</p> <p>12 had complications?</p> <p>13 A. It depends what you consider a</p> <p>14 complication.</p> <p>15 Q. Let's start broad.</p> <p>16 Just any complication, do you</p> <p>17 have an estimate of how many of the 3,000</p> <p>18 slings you've implanted the woman had a</p> <p>19 complication?</p> <p>20 A. I don't have my own estimate. I</p> <p>21 would go with pretty much what's in the</p> <p>22 literature, to be honest with you.</p> <p>23 Q. My question is more in your</p> <p>24 experience and estimate, taking the</p>	<p style="text-align: center;">Page 117</p> <p>1 slings you implanted, how many of those</p> <p>2 women had an erosion?</p> <p>3 A. From the 3,000, absolutely not.</p> <p>4 I don't have a reliable way.</p> <p>5 Q. And do you have a reliable way</p> <p>6 of estimating how many of the women, of</p> <p>7 the 3,000 women you implanted slings, how</p> <p>8 many of those women developed dyspareunia?</p> <p>9 A. I don't have that number</p> <p>10 available to me.</p> <p>11 Q. Do you have any reliable way of</p> <p>12 estimating how many of the women that you</p> <p>13 implanted slings in, your 3,000 women that</p> <p>14 you implanted slings in, how many of those</p> <p>15 women developed chronic pain?</p> <p>16 A. I don't have that number.</p> <p>17 However, I do believe that number is low.</p> <p>18 Q. If you could turn your</p> <p>19 attention, please, to page 8 of your</p> <p>20 report. At the top you say: "I have had</p> <p>21 extensive experience in treating</p> <p>22 complications after gynecologic</p> <p>23 surgeries."</p> <p>24 Do you see that?</p>

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<p>1 A. Yes.</p> <p>2 Q. (Continuing) "Including after</p> <p>3 Burch, needles procedures, autologous and</p> <p>4 midurethral sling procedures."</p> <p>5 Do you see that?</p> <p>6 A. Yes, I do.</p> <p>7 Q. Do you have any reliable</p> <p>8 estimate or method for estimating how many</p> <p>9 complications you've treated after a</p> <p>10 midurethral sling procedure?</p> <p>11 A. A number? I don't know. If I</p> <p>12 treated maybe a hundred or 50 to -- maybe</p> <p>13 50, 75.</p> <p>14 I don't really remember those</p> <p>15 numbers.</p> <p>16 Q. In preparing this report, did</p> <p>17 you undertake any investigation into how</p> <p>18 many women you have treated for</p> <p>19 complications from midurethral sling</p> <p>20 procedures?</p> <p>21 A. I didn't do a review of my</p> <p>22 studies of that, no.</p> <p>23 Q. Do you have that information</p> <p>24 available for you to review if you wanted</p>	<p>1 BY MR. BENTLEY:</p> <p>2 Q. During your medical residency,</p> <p>3 did you receive training on how to treat</p> <p>4 specifically complications of midurethral</p> <p>5 slings made out of polypropylene?</p> <p>6 A. Yes, because those slings have</p> <p>7 the same risks, except for erosion and/or</p> <p>8 exposure, as do the autologous slings, as</p> <p>9 do some Burch complications, and as do</p> <p>10 general complications of surgical</p> <p>11 procedures.</p> <p>12 Q. What training did you receive on</p> <p>13 how to treat complications from</p> <p>14 polypropylene slings during your</p> <p>15 residency?</p> <p>16 A. During my residency, I did not</p> <p>17 receive any training in polypropylene</p> <p>18 slings.</p> <p>19 I did receive training during my</p> <p>20 fellowship in synthetic slings in treating</p> <p>21 Gore-Tex slings that we had placed for</p> <p>22 synthetics.</p> <p>23 Q. What slings were available that</p> <p>24 were made out of Gore-Tex?</p>
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<p>1 to?</p> <p>2 A. Not easily available, no.</p> <p>3 Q. The next paragraph on page 8,</p> <p>4 you state that you received further</p> <p>5 training in preventing, identifying and</p> <p>6 treating surgical complications during</p> <p>7 residency.</p> <p>8 Do you see that?</p> <p>9 A. Yes.</p> <p>10 Q. Your residency was before the</p> <p>11 midurethral slings were available,</p> <p>12 correct?</p> <p>13 A. Correct.</p> <p>14 Q. So you couldn't have received</p> <p>15 training on how to treat midurethral</p> <p>16 slings, could you have?</p> <p>17 A. Well, all slings have the same</p> <p>18 complications except for synthetic slings</p> <p>19 which may have complication -- which do</p> <p>20 have a complication of erosion or</p> <p>21 exposure. And we can debate whether or</p> <p>22 not autologous or biologic slings have</p> <p>23 that risk or not.</p> <p>24 MR. BENTLEY: Let me re-ask it.</p>	<p>1 A. So, you would cut a sheet of</p> <p>2 Gore-Tex at that point in time and use</p> <p>3 that as your implantable.</p> <p>4 In the late -- in the 1990s,</p> <p>5 there was no specific indication for any</p> <p>6 of the meshes that people were using at</p> <p>7 that point in time, whether it was Marlex,</p> <p>8 Mersilene, Gore-Tex. People were cutting</p> <p>9 their own pieces and using them as the</p> <p>10 sling.</p> <p>11 Q. There was no sling product</p> <p>12 manufactured that was made of Gore-Tex; is</p> <p>13 that correct?</p> <p>14 A. Gore-Tex never made a sling,</p> <p>15 that is correct.</p> <p>16 Q. Do you have an opinion as to</p> <p>17 whether the Gore-Tex slings were safe and</p> <p>18 effective?</p> <p>19 A. I think the Gore-Tex slings had</p> <p>20 a high complication rate.</p> <p>21 Q. Do you have any understanding of</p> <p>22 why they had a high complication rate?</p> <p>23 A. They're a microporous mesh and</p> <p>24 the sling would get encapsulated as</p>

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<p>1 opposed to integration into the tissue, 2 and that would have been one of the 3 reasons why they had a high complication 4 rate.</p> <p>5 Q. So, I think I understand. 6 Your testimony is that the 7 Gore-Tex slings had a high complication 8 rate because they were microporous, in 9 part?</p> <p>10 A. Yes.</p> <p>11 Q. And the slings, the size of 12 their pores is an aspect of the design of 13 the mesh; is that correct?</p> <p>14 A. Correct.</p> <p>15 Q. And the geometry of the mesh is 16 part of the design of the product, 17 correct?</p> <p>18 A. What do you mean by "geometry," 19 that it's linear?</p> <p>20 Q. The mesh is a knitted product 21 that's they take a monofilament 22 polypropylene and knit it into a mesh, 23 correct?</p> <p>24 A. Correct.</p>	<p>1 slings available, correct? 2 A. Not that I'm aware of, correct. 3 Q. And you're not implanting 4 Gore-Tex slings today, right? 5 A. No. 6 Q. Doctor, you learned the Burch 7 procedure during your residency, correct? 8 A. I was exposed to it in 9 residency. I really learned it in 10 fellowship. 11 Q. Thank you. 12 And you used it as a frequent 13 treatment for incontinence early on in 14 your career, correct? 15 A. Yes, it was a primary procedure 16 for incontinence. 17 Q. Did you have good results with 18 the Burch? Doing that procedure, did you 19 have good results? 20 A. Yes. 21 Q. And by "good results," you had 22 good efficacy rates? 23 A. Yes. 24 Q. And low complication rates?</p>
<p>1 Q. And it creates a certain pattern 2 or a pore structure, correct? 3 A. Correct.</p> <p>4 Q. And there's large pores and 5 smaller pores and different pores, 6 correct?</p> <p>7 A. Correct.</p> <p>8 Q. And I believe it's your 9 testimony that the Gore-Tex slings had a 10 pore complication that fell apart because 11 they were microporous?</p> <p>12 A. Correct.</p> <p>13 Q. Which is the geometry of the 14 mesh or the knitting design, correct?</p> <p>15 A. Correct.</p> <p>16 Q. Okay. Do you have an opinion as 17 to whether or not it was the Gore-Tex 18 material inherently causing the 19 complication, or was it the geometry of 20 the Gore-Tex pores that was causing the 21 complications?</p> <p>22 A. I don't have an opinion on 23 either.</p> <p>24 Q. But today there's no Gore-Tex</p>	<p>1 A. Depends what you consider low. 2 There were complications associated with 3 the Burch procedure, but it's a good 4 procedure. 5 Q. At least in your hands, it was a 6 good procedure and safe and effective; is 7 that fair? 8 A. Yes. 9 Q. Do you have any estimate as to 10 what your complication rate would have 11 been when you were doing the Burch 12 procedure to treat women with 13 incontinence? 14 A. Once again, somewhere in the -- 15 depends on what you consider a 16 complication, if a wound infection is a 17 complication. So I think overall, I don't 18 have a -- that's really far back going 19 remembering, but if we're taking all 20 complications, wound infections, pain, you 21 know, could have been six to eight 22 percent. 23 Q. Would you consider that low? 24 A. Depends on what you're</p>

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<p>1 considering a complication, again, and 2 what is a major complication, what's a 3 minor complication. 4 The most common complication 5 from all these anti-incontinence 6 procedures is actually a urinary tract 7 infection. Many people don't consider 8 that a complication. 9 So it depends on what you 10 consider low and high. 11 Q. Recurrent UTIs could be a more 12 serious complication; is that fair? 13 A. Recurrent UTIs could be more 14 bothersome than just one UTI, for sure. 15 Q. When you meet with women today 16 that are suffering from incontinence, you 17 discuss the various treatments, as we 18 discussed earlier, correct? 19 A. Mm-hm. 20 Q. Yes? 21 A. Yes. 22 I'm sorry. Once again I 23 apologize. My fault. 24 Q. And you discuss non-surgical and</p>	<p>1 potential option for treating the 2 incontinence, what do you generally tell 3 them is your complication rate with the 4 Burch procedure? 5 A. So, I would tell them it's not a 6 commonly performed procedure today that I 7 do, as the midurethral sling has sort of 8 become the standard in treatment for 9 stress incontinence, which has been 10 ratified or promoted or agreed upon by the 11 major societies in the U.S. and 12 internationally. I tell them my 13 complication rate is low with the Burch 14 procedure. However, the overall morbidity 15 with abdominal incision, recovery is 16 longer associated with the Burch 17 procedure, and the data does not show that 18 the Burch procedure has a better overall 19 success rate than the midurethral slings. 20 Q. So, you want to give patients 21 complete knowledge so they can make a full 22 and informed decision; is that fair? 23 A. Yes, I do. 24 Q. And when you discuss potential</p>
<p>1 surgical interventions, correct? 2 A. Correct. 3 Q. And when you discuss surgical 4 interventions, you discuss the midurethral 5 slings, correct? 6 A. Correct. 7 Q. And do you still discuss the 8 Burch procedure as one of the options 9 today? 10 A. I mention it to them. Every 11 single -- I try to give every single 12 patient the IUGA handout, the 13 International Urogynecological Association 14 handout on stress incontinence on the 15 patient's first visit. So in there it's 16 described all the options. So if the 17 patient doesn't remember what the options 18 are, they can take it home and read it. I 19 encourage them to go to the Web site. I 20 encourage them to do their own research on 21 the options, as well as the products 22 themselves. 23 Q. And when you discuss the Burch 24 procedure today with your patients as a</p>	<p>1 treatment options for incontinence, you 2 give them the option of Burch; is that 3 correct? 4 A. It's in there, yes. 5 Q. And what do you tell your 6 patients about the complication rate? Do 7 you only classify it as low, or do you 8 give them an estimated complication rate? 9 A. So, that's a really hard 10 question to answer about what the 11 complication rate is and even the 12 percentages are available even amongst the 13 studies that you're going to look at. I 14 will tell them it is low. The likelihood 15 of them having major complication, death 16 is a major complication, the likelihood of 17 that happening is low, but I try not to 18 quantify exactly what low and rare is, and 19 we try to come to an understanding with 20 the patient in order to figure out what's 21 going to be the most appropriate treatment 22 that they would like to go forward with. 23 Q. Do you give your patients a 24 range of what you anticipate the</p>

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<p>1 complication rate would be for Burch?</p> <p>2 A. They don't ask that.</p> <p>3 Q. So you don't tell them?</p> <p>4 A. I don't give them a range of</p> <p>5 what the complication rate will be.</p> <p>6 Q. And similarly, do you give your</p> <p>7 patients an estimate of what you think the</p> <p>8 efficacy would be for Burch?</p> <p>9 A. I say they're comparable. And I</p> <p>10 usually would say somewhere around 80 to</p> <p>11 85 percent success rate for a midurethral</p> <p>12 sling, so you can extrapolate that. It's</p> <p>13 probably around the same for a Burch</p> <p>14 procedure.</p> <p>15 Q. You haven't undergone any type</p> <p>16 of statistical analysis to figure out what</p> <p>17 the true complication rate is for Burch,</p> <p>18 have you?</p> <p>19 A. Myself, I have not done that. I</p> <p>20 go by the literature and the systemic</p> <p>21 reviews and the Level I evidence.</p> <p>22 Q. And in preparing this report,</p> <p>23 you didn't do a statistical analysis of</p> <p>24 what you think the true rate is of</p>	<p>1 systemic reviews and systematic reviews,</p> <p>2 or is it just kind of synonymous?</p> <p>3 A. I use them interchangeably.</p> <p>4 Q. We talked about you have</p> <p>5 experience treating complications,</p> <p>6 including after Burch procedures; is that</p> <p>7 correct?</p> <p>8 A. Yes.</p> <p>9 Q. How often do you see patients</p> <p>10 that have had a complication from Burch?</p> <p>11 A. We don't see it commonly and</p> <p>12 it's rare because there aren't that many</p> <p>13 Burch procedures being done anymore.</p> <p>14 Q. Did you used to see more</p> <p>15 patients that had complications from</p> <p>16 Burch?</p> <p>17 A. Yes.</p> <p>18 Q. And what would the complications</p> <p>19 that you --</p> <p>20 MR. BENTLEY: Let me rephrase</p> <p>21 that.</p> <p>22 Q. The women that you saw that had</p> <p>23 complications from Burch back when Burch</p> <p>24 was done more commonly, what were the</p>
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<p>1 complications of Burch?</p> <p>2 A. I personally did not perform a</p> <p>3 systemic analysis.</p> <p>4 I did my own Pub Med searches.</p> <p>5 Q. You don't have SAS on your</p> <p>6 computer at home, do you?</p> <p>7 A. No.</p> <p>8 Q. And similarly, you didn't do a</p> <p>9 statistical analysis of what you think the</p> <p>10 true complication rate is of polypropylene</p> <p>11 slings, correct?</p> <p>12 A. I did not do a -- my own</p> <p>13 systemic review. I read the Level I</p> <p>14 evidence, and I'm aware of the Level I</p> <p>15 evidence that I've been reading throughout</p> <p>16 my entire career.</p> <p>17 Q. What is the definition of Level</p> <p>18 I evidence?</p> <p>19 A. So, Level I evidence is</p> <p>20 meta-analysis and systemic reviews. After</p> <p>21 that would be randomized control trials.</p> <p>22 So, I try to stick with Level I</p> <p>23 and Level II evidence if it's available.</p> <p>24 Q. Is there a difference between</p>	<p>1 complications that you saw and treated?</p> <p>2 A. So, complications could be</p> <p>3 urinary retention, voiding dysfunction,</p> <p>4 suture erosion, hematoma developing from</p> <p>5 the incision, pain with the incision,</p> <p>6 infection with the incision.</p> <p>7 THE WITNESS: Can you read back</p> <p>8 what I told him already?</p> <p>9 (The requested portion of the</p> <p>10 record was read by the Court Reporter.)</p> <p>11 A. And prolapse occurring after the</p> <p>12 Burch procedure.</p> <p>13 Q. And what surgical interventions</p> <p>14 did you have to perform to treat</p> <p>15 complications that might have arisen from</p> <p>16 Burch?</p> <p>17 A. So, it depends on what the</p> <p>18 complication was. Sometimes there were</p> <p>19 sinus tracts that developed abdominally to</p> <p>20 the suture that we put in. So we would</p> <p>21 need to go back in abdominally and remove</p> <p>22 that permanent suture. Sometimes the</p> <p>23 patient would develop urinary retention or</p> <p>24 significant voiding dysfunction, where we</p>

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<p>1 would need to go in vaginally and do a 2 urethrolysis. Those are the more common 3 procedures we were doing. 4 If someone had a prolapse 5 failure afterwards and wanted treatment 6 for that, we would go in and treat their 7 prolapse. 8 Q. What kind of sutures were you 9 using to do your Burch procedures? 10 A. 2-0 Gore-Tex sutures is what I 11 used and what I would still use today. 12 Q. Doctor, when we talk about mesh 13 erosion, sometimes I see "exposure" and 14 "extrusion." 15 Do you have some definition that 16 differentiates those three words, or are 17 they kind of interchangeable? 18 A. So, what I like to use in my 19 documentation if I'm writing the note, I 20 prefer to use the word "exposure" when 21 there's mesh visible in the vagina. I 22 prefer to use "erosion" when mesh has 23 migrated into a visceral organ, 24 specifically most commonly here would be</p>	<p>1 correct? 2 A. An exposure from a TVT or any 3 type of midurethral sling, as a general 4 rule, is not that difficult a procedure to 5 perform. It's right there in front of 6 you. It's a vaginal procedure and you 7 don't -- it's not a terribly difficult 8 procedure. 9 Q. Is it all -- 10 A. And you know what, you don't 11 have to perform it all the time. If it's 12 not bothering the patient, you can leave 13 it. 14 Q. But if it's symptomatic, you 15 need to do some sort of intervention, 16 correct? 17 A. Correct. 18 Q. And is it always performed on an 19 outpatient basis? 20 A. Not always. Sometimes I will 21 try to, and I'll discuss with the patient 22 of what they would rather me do, but 23 sometimes in the office we can try to, if 24 it's just a little piece of an edge</p>
<p>1 either in urethra or into bladder. 2 Although mesh, and depending on what type 3 of meshes we're talking about, they can 4 migrate to other places. 5 Q. And you don't use "extrusion" in 6 your practice? 7 A. Not commonly. It's not a common 8 term that I use. 9 Q. On page 4 of your report, 10 there's a paragraph that starts -- I'm 11 sorry, on page 35 of your report there's a 12 paragraph that starts: "The surgical 13 risks". 14 Do you see that? 15 A. Yep. 16 Q. About halfway down you say: 17 "Although if necessary, surgical 18 correction for exposure is a relatively 19 simple procedure performed on an 20 outpatient basis." 21 Do you see that? 22 A. Yes, I do. 23 Q. Sometimes it's not relatively 24 simple to fix the exposure; isn't that</p>	<p>1 eroding through, that we can try cutting 2 that little piece off in the office and 3 giving some vagina estrogen. It doesn't 4 always have to be. 5 Q. Okay. And using your definition 6 that you just gave me, now I understand. 7 Your next sentence you say: 8 "Erosion of mesh into the bladder area is 9 rare." 10 Is the surgical intervention to 11 fix an erosion more invasive than the 12 surgical intervention to fix an exposure? 13 A. I don't know if I want to use 14 the term "invasive." 15 I can use the term "a little 16 more complicated." 17 Q. And by "complicated," there's 18 going to be more dissection, correct? 19 A. There's more dissection. If 20 there's an erosion into the bladder, I 21 need to repair the bladder. And I have to 22 get to the bladder somehow, so I either 23 have to go in abdominally or go in 24 vaginally to repair those erosions into</p>

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<p>1 those areas.</p> <p>2 Q. And that's not like the simple</p> <p>3 office procedure?</p> <p>4 A. That is not a simple office</p> <p>5 procedure. But once again, those are --</p> <p>6 those do not happen commonly.</p> <p>7 Q. In your experience, what's the</p> <p>8 percentage of the women that you implant</p> <p>9 with polypropylene slings that --</p> <p>10 A. Sorry, can you start over again?</p> <p>11 Q. Sure.</p> <p>12 In your experience implanting</p> <p>13 polypropylene slings, do you have an</p> <p>14 estimate of how many women suffer from</p> <p>15 voiding difficulties after the procedure?</p> <p>16 A. I don't have an estimate of my</p> <p>17 own.</p> <p>18 Q. I may have already asked this.</p> <p>19 In your experience doing the</p> <p>20 Burch procedure to treat incontinence, do</p> <p>21 you have an estimate of what percent of</p> <p>22 the women suffer from voiding difficulties</p> <p>23 after the procedure?</p> <p>24 A. I don't have an estimate for</p>	<p>1 around it, I apologize, and if someone is</p> <p>2 complaining of difficulty urinating, she</p> <p>3 feels that she's got the urgency, it's a</p> <p>4 very slow stream, it's dribbling, she has</p> <p>5 urinary retention, that may indicate to me</p> <p>6 that this sling has gotten a little too</p> <p>7 tight for her and we need to go back to</p> <p>8 the operating room to do a revision or cut</p> <p>9 the sling.</p> <p>10 Q. Do you have an estimate of how</p> <p>11 often the women that you implant these</p> <p>12 slings in have those obstructive voiding</p> <p>13 complications?</p> <p>14 A. I have not done a systemic</p> <p>15 review of my patients.</p> <p>16 However, I think I'm cutting</p> <p>17 about one sling a year, so it's about a</p> <p>18 half, maybe a half percent or something</p> <p>19 like that that I'm going back in, that I</p> <p>20 know of, on these patients.</p> <p>21 Q. So maybe one out of</p> <p>22 approximately 175 slings per year that you</p> <p>23 implant the woman is going to develop some</p> <p>24 obstructive voiding problem; is that</p>
Page 139	Page 141
<p>1 that, no.</p> <p>2 Q. Do you have some standard of</p> <p>3 what you consider an acceptable rate of</p> <p>4 voiding difficulty for a surgery to treat</p> <p>5 incontinence?</p> <p>6 A. So, that's also a difficult</p> <p>7 question 'cause we need to understand what</p> <p>8 voiding dysfunction is, and once again is</p> <p>9 the voiding dysfunction symptomatic or not</p> <p>10 symptomatic. Many women's sometimes will</p> <p>11 just tell me their voiding pattern changes</p> <p>12 after you put a sling in. We're doing</p> <p>13 surgery on them.</p> <p>14 So that's why I don't have a</p> <p>15 great estimate for you 'cause voiding</p> <p>16 dysfunction is really a hodgepodge of</p> <p>17 symptoms that a patient may have.</p> <p>18 Q. What voiding difficulty symptoms</p> <p>19 would require surgical intervention?</p> <p>20 A. So, if there's any evidence of</p> <p>21 obstructed voiding, that the sling has</p> <p>22 some reason -- for some reason got a</p> <p>23 little too tight around the urethra, or</p> <p>24 underneath the urethra as opposed to</p>	<p>1 fair?</p> <p>2 A. That's going to develop some</p> <p>3 kind of obstructive voiding problem that I</p> <p>4 need to go back in and cut the sling, yes.</p> <p>5 Q. And that's because the sling had</p> <p>6 gotten a little too tight maybe around the</p> <p>7 urethra; is that correct?</p> <p>8 A. Yeah. I pretty much put the</p> <p>9 sling in the same way. There's some</p> <p>10 people who develop more scar and there's</p> <p>11 some people who develop less scar. And</p> <p>12 yes, the sling has scarred in and gotten a</p> <p>13 little too tight underneath the urethra</p> <p>14 causing the obstruction, causing the</p> <p>15 voiding difficulty.</p> <p>16 Q. And that's not because you put</p> <p>17 it in incorrectly, is it?</p> <p>18 A. I don't think so. It's a known,</p> <p>19 commonly known complication for a</p> <p>20 midurethral sling. It's a commonly known</p> <p>21 complication for any type of</p> <p>22 anti-incontinence procedure that we're</p> <p>23 performing.</p> <p>24 Q. And you put the sling in with</p>

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<p>1 the same --</p> <p>2 MR. BENTLEY: Let me rephrase</p> <p>3 that.</p> <p>4 Q. When you put the sling in, you</p> <p>5 always put them in tension-free, correct?</p> <p>6 A. Correct.</p> <p>7 And I understand tension-free is</p> <p>8 difficult. It's just like when we're</p> <p>9 doing obstetrics and we don't do traction</p> <p>10 on the baby's head.</p> <p>11 So, tension-free is one of those</p> <p>12 words that we put in open and closed</p> <p>13 quotations.</p> <p>14 Q. You don't put the slings in with</p> <p>15 tension; is that fair?</p> <p>16 A. Try not to, yes.</p> <p>17 Q. But sometimes though some of the</p> <p>18 women still develop obstructive voiding</p> <p>19 because the sling got a little too tight?</p> <p>20 A. Correct, yes.</p> <p>21 And once again, commonly known.</p> <p>22 Q. Those women that you sling that</p> <p>23 develop obstructive voiding because the</p> <p>24 sling got too tight, when in your</p>	<p>1 lower quality of evidence, and finally</p> <p>2 case series provide the lowest (Level IV.)"</p> <p>3 Is that correct?</p> <p>4 A. Correct.</p> <p>5 Q. Is that consistent with your</p> <p>6 approach to evaluating literature in your</p> <p>7 practice and in this report?</p> <p>8 A. It is today.</p> <p>9 Q. When you say "it is today," has</p> <p>10 that changed in your experience, or have</p> <p>11 you always considered Level I to be</p> <p>12 systemic or systematic reviews of RCTs?</p> <p>13 A. I've always considered that, but</p> <p>14 there wasn't a lot of good Level I data</p> <p>15 available in the late '90s, and early</p> <p>16 2000s.</p> <p>17 Q. Right. So, the levels of data,</p> <p>18 the definitions of what Level I data,</p> <p>19 that's nothing new, right?</p> <p>20 A. Yeah, I don't know when Oxford</p> <p>21 came out with it, but it's been available,</p> <p>22 yes.</p> <p>23 Q. And all things equal, you would</p> <p>24 rather look at Level I data than Level II</p>
<p style="text-align: center;">Page 143</p> <p>1 experience does that occur; what time</p> <p>2 frame after the implant?</p> <p>3 A. Generally within the first year</p> <p>4 is I would see that.</p> <p>5 Q. Doctor, could you please turn to</p> <p>6 page 7 of your report. We started talking</p> <p>7 about this a little bit.</p> <p>8 I did it again, sorry. Page 50.</p> <p>9 A. No problem. Going back.</p> <p>10 Q. Going back forward.</p> <p>11 A. Yes.</p> <p>12 Q. All right. On page 50.</p> <p>13 A. Yes.</p> <p>14 Q. (Reading) "The most extensively</p> <p>15 studied surgical treatment."</p> <p>16 Do you see that paragraph that</p> <p>17 begins with that?</p> <p>18 A. Yes.</p> <p>19 Q. A little bit down in that</p> <p>20 paragraph you say: "Symptomatic reviews</p> <p>21 of randomized control trials (Level I)</p> <p>22 provide the most reliable data followed by</p> <p>23 individualized randomized trials (Level</p> <p>24 II), cohort studies (Level III), provide</p>	<p style="text-align: center;">Page 145</p> <p>1 and Level III, correct?</p> <p>2 A. Correct.</p> <p>3 Q. What's your definition of Level</p> <p>4 II data?</p> <p>5 A. Level II are individualized,</p> <p>6 randomized control trials, ones that may</p> <p>7 have not been so -- and ones that --</p> <p>8 mostly randomized control trials and ones</p> <p>9 that maybe were poorly structured or may</p> <p>10 have had a large loss to follow-up.</p> <p>11 They're not as strong as the</p> <p>12 well-performed randomized control trials.</p> <p>13 Q. Could well-performed large</p> <p>14 multicenter RCTs be Level I evidence?</p> <p>15 A. It depends on what other data's</p> <p>16 available.</p> <p>17 Q. And cohort studies are lower</p> <p>18 level of evidence, or Level III; is that</p> <p>19 correct?</p> <p>20 A. Yes, cohort and case control</p> <p>21 studies are lower levels.</p> <p>22 Q. So, when you're looking --</p> <p>23 MR. BENTLEY: Let me rephrase</p> <p>24 that.</p>

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<p>1 Q. When you are talking about, 2 quotes, reliable evidence, quote, does 3 that mean that you're looking for Level I 4 or Level II evidence?</p> <p>5 A. I'm always looking for Level I 6 or Level II. If that doesn't exist, we 7 need to go to the III and the IV.</p> <p>8 Q. So, could you please turn to 9 page 42 of your report.</p> <p>10 A. Okay.</p> <p>11 Q. In that middle paragraph that 12 starts off: "I was an early adopter of 13 TTVT."</p> <p>14 Do you see that?</p> <p>15 A. Yes.</p> <p>16 Q. Do you see about halfway down 17 say: "I have seen reports and testimony 18 from experts, including Dr. Bruce 19 Rosenzweig, suggesting that both 20 mechanically-cut TTVT and laser-cut TTVT are 21 defective."</p> <p>22 Do you see that?</p> <p>23 A. I see that.</p> <p>24 Q. The next sentence you put:</p>	<p>1 report and reviewed the studies that he 2 looked at and discussed, correct?</p> <p>3 A. Yes. I don't have it committed 4 to memory, but I did review his report. 5 He's written a number of them.</p> <p>6 Q. And you determined that the 7 evidence he was looking at was not 8 reliable scientific data, according to 9 your report, correct?</p> <p>10 A. According to my report, I did 11 not find any reliable clinical data to 12 support his claims.</p> <p>13 Q. And the next sentence you 14 discuss the Thubert 2016 study that showed 15 TTVT versus TTVT-Exact had similar peri and 16 postoperative complications.</p> <p>17 Do you see that?</p> <p>18 A. Yes, I do.</p> <p>19 Q. Then you state: "Both TTVT and 20 TTVT-Exact resulting in 0 percent mesh 21 exposure"?</p> <p>22 A. Yes, in that study.</p> <p>23 Q. And you don't have any 24 discussion of Dr. Rosenzweig's opinions or</p>
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<p>1 "These opinions are not based on reliable 2 scientific data."</p> <p>3 A. Correct, because later on in my 4 report, and we can move to that page if 5 you like, there is some data on 6 mechanically-cut slings versus laser-cut 7 slings which did not show any difference.</p> <p>8 Q. So, just to be clear, in this 9 sentence when you're talking about it's 10 not reliable, you're not making a 11 reference to whether or not it's Level I, 12 Level II, Level III; is that fair?</p> <p>13 A. I am not.</p> <p>14 When I state that it's not 15 reliable -- where does it say -- okay. I 16 have searched -- there are no reliable 17 clinical studies to back what he says, 18 that I'm aware of. And when I say "he", 19 it's Dr. Rosenzweig.</p> <p>20 If you can produce some data 21 that shows that mechanically-cut TTVT and 22 laser-cut TTVT have any differences, I'd be 23 glad to look at those.</p> <p>24 Q. So you reviewed Dr. Rosenzweig's</p>	<p>1 data regarding laser-cut or 2 mechanically-cut, in this paragraph at 3 least, do you?</p> <p>4 A. In this paragraph, I do not. I 5 do remember Dr. Rosenzweig saying he has 6 implanted about 50 or 75 midurethral 7 slings, and I don't think he has anywhere 8 near the experience that I do in 9 implanting midurethral slings, nor the 10 clinical experience.</p> <p>11 Q. Okay. I'm not really talking 12 about Dr. Rosenzweig's personal 13 experience.</p> <p>14 A. Okay.</p> <p>15 Q. In his report he discusses some 16 literature.</p> <p>17 Do you recall reading that?</p> <p>18 A. Yeah, he discussed literature.</p> <p>19 Once again, if you want to pull 20 out his report, I'm more than welcome to 21 look at it with you, but I'm not going to 22 remember it verbatim.</p> <p>23 Q. And you came to the conclusion 24 that his opinions were not based on</p>

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<p>1 reliable scientific data, correct?</p> <p>2 A. His opinions were not based on</p> <p>3 any reliable data that I was able to find.</p> <p>4 Q. So you looked at the data that</p> <p>5 he reviewed and cited to, correct?</p> <p>6 A. I did my Pub Med searches in</p> <p>7 terms to try to find the differences</p> <p>8 between the TVTs and TVT-Exact and</p> <p>9 laser-cut and non-laser-cut, Boston</p> <p>10 Scientific meshes and not Boston</p> <p>11 Scientific meshes, and I tried to find the</p> <p>12 data where it said that mechanically-cut</p> <p>13 was any better or worse than a laser-cut.</p> <p>14 MR. ROSENBLATT: He's asking if</p> <p>15 you reviewed the studies that he</p> <p>16 actually cited in the body of his</p> <p>17 report.</p> <p>18 THE WITNESS: So, I went through</p> <p>19 his --</p> <p>20 MR. BENTLEY: Thank you.</p> <p>21 A. Okay. I went through the</p> <p>22 reliance list, and I actually went through</p> <p>23 some of the reports and studies from his</p> <p>24 reports.</p>	<p>1 particulars.</p> <p>2 But once again, if we pull out</p> <p>3 his report, I'm willing to go through that</p> <p>4 with you why I reached that conclusion.</p> <p>5 Q. Okay. I believe you testified</p> <p>6 that you performed a Pub Med search, is</p> <p>7 that what you said?</p> <p>8 A. Yes.</p> <p>9 Q. And you performed a Pub Med</p> <p>10 search in response to Dr. Rosenzweig's</p> <p>11 laser-cut opinions?</p> <p>12 A. No, I didn't put Rosenzweig in</p> <p>13 there because he hasn't written any</p> <p>14 scientific paper on this.</p> <p>15 Q. Right.</p> <p>16 A. I would have put in TVT</p> <p>17 complications. I would have put in mesh</p> <p>18 erosion, mesh exposure, mesh extrusion. I</p> <p>19 can't remember every single term that I</p> <p>20 went ahead and used in order to do my</p> <p>21 searches. And I would have tried to find</p> <p>22 what he did and where he based his</p> <p>23 opinions on and what I based my opinions</p> <p>24 on.</p>
<p style="text-align: center;">Page 151</p> <p>1 Do I recall if I remember seeing</p> <p>2 one on specific on mechanical and laser, I</p> <p>3 don't.</p> <p>4 But once again, if we can pull</p> <p>5 out his study and see the citations, I'd</p> <p>6 be glad to review those would be.</p> <p>7 Q. I'm just trying to -- there's</p> <p>8 nowhere in your report that I found that</p> <p>9 discusses your conclusion that Dr.</p> <p>10 Rosenzweig's evidence that he relied upon</p> <p>11 was -- I don't understand how you reached</p> <p>12 that it's not reliable.</p> <p>13 A. Well, if we turn the page, we</p> <p>14 can look at studies by Lim and Agarwala.</p> <p>15 Q. And that's not -- I appreciate</p> <p>16 that you're citing to some other evidence.</p> <p>17 I'm trying to see how you got to your</p> <p>18 conclusion that the evidence that Dr.</p> <p>19 Rosenzweig didn't rely upon reliable</p> <p>20 evidence, and if you have any opinion</p> <p>21 today as to your concern or criticism of</p> <p>22 the studies that Dr. Rosenzweig cited, can</p> <p>23 you share those with me, please?</p> <p>24 A. I don't recall in the</p>	<p style="text-align: center;">Page 153</p> <p>1 Q. You have no record of what key</p> <p>2 word searches you've done?</p> <p>3 A. I did not keep a running tab,</p> <p>4 no.</p> <p>5 Q. We already talked about you</p> <p>6 didn't do a systemic literature review,</p> <p>7 correct?</p> <p>8 A. No. I did my Pub Med searches</p> <p>9 and sometimes on Google Scholar, and then</p> <p>10 when I got to one paper, I would look at</p> <p>11 the references on that paper.</p> <p>12 You should see my library room</p> <p>13 in my office. My wife ain't happy.</p> <p>14 Q. You didn't have a preset</p> <p>15 inclusion/exclusion criteria?</p> <p>16 A. What systemic searches and stuff</p> <p>17 like that?</p> <p>18 Q. Correct.</p> <p>19 A. No, I didn't write a paper and</p> <p>20 include that kind of stuff.</p> <p>21 Q. Do you have any type of record</p> <p>22 of how many articles your key word</p> <p>23 searches turned up?</p> <p>24 MR. ROSENBLATT: Object to form.</p>

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<p>1 BY MR. BENTLEY:</p> <p>2 Q. Do you have any reliable record</p> <p>3 of how many articles popped up in your Pub</p> <p>4 Med search when you did a key word</p> <p>5 search --</p> <p>6 A. I don't remember, but I can tell</p> <p>7 you that I've been reviewing literature</p> <p>8 throughout my entire career. I've been</p> <p>9 reviewing the literature that's available</p> <p>10 on slings, on prolapse. I did an</p> <p>11 extensive search and even reviewed more</p> <p>12 literature and more articles, many of</p> <p>13 which I had seen in the past, for this</p> <p>14 particular report.</p> <p>15 Q. Are there some studies that you</p> <p>16 found more powerful or compelling than</p> <p>17 others?</p> <p>18 A. As I stated before, I always put</p> <p>19 more emphasis and I rely more on Level I</p> <p>20 and Level II data than Level III and IV if</p> <p>21 that data is available.</p> <p>22 Q. And if you had any type of</p> <p>23 opinion as to which evidence was more</p> <p>24 powerful or compelling, would you have</p>	<p>1 we're talking about here, the TVT and</p> <p>2 TTVT-Exact, once those are implanted, do</p> <p>3 they cause a chronic inflammatory</p> <p>4 reaction?</p> <p>5 A. Yes, when you implant a</p> <p>6 polypropylene or any type of synthetic</p> <p>7 slings, or any type of synthetic material</p> <p>8 for that matter, you're going to get a</p> <p>9 chronic inflammatory reaction.</p> <p>10 Although, polypropylene slings</p> <p>11 as compared to other slings have a -- seem</p> <p>12 to have a lower chronic inflammatory</p> <p>13 reaction than things that we used in the</p> <p>14 past.</p> <p>15 Q. Do you have an understanding as</p> <p>16 to whether the construction of the mesh</p> <p>17 influences the level of inflammation?</p> <p>18 A. Yes, I do.</p> <p>19 Q. And what is that?</p> <p>20 A. So, the pore size will matter.</p> <p>21 So you would like a pore size above 1</p> <p>22 millimeter. You want a type 1 macroporous</p> <p>23 mesh that is monofilament as opposed to</p> <p>24 multifilament. So there are</p>
<p>1 provided those opinions in this report?</p> <p>2 A. I would have tried, yes.</p> <p>3 Q. And in this report you include a</p> <p>4 lot of data, correct?</p> <p>5 A. I think I did, yeah.</p> <p>6 Q. And is that data limited to any</p> <p>7 specific threshold of Level I or Level II?</p> <p>8 How did you go about choosing</p> <p>9 which articles to put in here?</p> <p>10 A. Once again, from my searches, if</p> <p>11 Level I data existed, I tried to include</p> <p>12 the Level I data. So with the highest</p> <p>13 level of data that existed for that</p> <p>14 particular topic, I tried to include.</p> <p>15 Q. Doctor, would you agree that</p> <p>16 polypropylene mesh, once implanted, causes</p> <p>17 a chronic inflammatory reaction?</p> <p>18 MR. ROSENBLATT: Object to form.</p> <p>19 A. Any kind of foreign body that</p> <p>20 you're going to place in the body is going</p> <p>21 to create a foreign body reaction.</p> <p>22 Q. Right. It's a little more</p> <p>23 specific.</p> <p>24 The polypropylene slings that</p>	<p>1 characteristics of the fiber and there are</p> <p>2 characteristics of the knit that both, as</p> <p>3 well as the weight of density of the</p> <p>4 fiber, that come into play when you put a</p> <p>5 polypropylene sling in.</p> <p>6 Q. Do you have an opinion as to</p> <p>7 whether or not the cutting method of the</p> <p>8 mesh influences the inflammation?</p> <p>9 A. In my experience, the laser-cut</p> <p>10 and mechanically-cut have functioned the</p> <p>11 same and come to the -- and have provided</p> <p>12 the same results in efficacy as well as</p> <p>13 safety.</p> <p>14 Q. My question is do you have an</p> <p>15 opinion as to whether the cutting method</p> <p>16 has any type of impact on the inflammatory</p> <p>17 response once implanted?</p> <p>18 A. My opinion is that cutting or</p> <p>19 laser-cut does not make a difference.</p> <p>20 Q. It doesn't make any difference</p> <p>21 to the inflammatory --</p> <p>22 A. On the inflammatory response.</p> <p>23 Q. Thank you.</p> <p>24 So, you've testified that the</p>
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<p>1 polypropylene slings do have a chronic 2 inflammatory reaction, correct? 3 A. Yes. 4 Q. So, if the inflammatory reaction 5 was instead described as transient, would 6 that be incorrect? 7 A. No, not necessarily, 'cause if 8 you remember, or if you recall, or I'll 9 tell you, there is two types of 10 inflammatory reactions that occur. 11 There's an acute inflammatory reaction and 12 a chronic inflammatory reaction that 13 occurs when you implant any foreign body. 14 So the acute one is transient, goes away. 15 Q. So the chronic reaction is 16 chronic, is that what you're saying? 17 A. The body responds to that 18 foreign body that's placed in, whether 19 it's a suture material, whether it's a 20 polypropylene mesh. Generally these 21 products are safe and don't -- don't cause 22 complications. But yes, the body still 23 knows that it's there. That part of the 24 design was good. For the body.</p>	<p>1 chronic inflammatory reaction going on. 2 So what I usually will discuss is with 3 them the -- the acute inflammatory 4 reaction, which is a little pain and 5 vaginal discharge that you can get with 6 these slings, as opposed to the, 7 quote/unquote, chronic inflammatory 8 reaction. 9 And, don't kid yourself, I tell 10 every single patient that this is a 11 permanent implant. This is not meant to 12 go away. It is not meant to be removed if 13 it is working. 14 Q. And if there's a problem, you 15 still don't remove the whole mesh; you 16 cut the piece that is sticking out and 17 leave the remainder of the mesh, correct? 18 A. Once again, depends what the 19 problem is. With slings, the most common 20 problem is an exposure or retention. Then 21 we would just either cut or remove that 22 portion. We would not go after the entire 23 rest of the sling because that just 24 increases the morbidity to the patient</p>
<p>Page 159</p> <p>1 Q. So, if you were discussing the 2 inflammatory response that happens after 3 implanting this mesh in a woman's body, if 4 you were discussing that with one of your 5 patients, and this mesh is a permanent 6 implant, correct? 7 A. Correct. 8 Q. It's in a woman's body until you 9 take it out, correct? 10 A. It's intended to last and it's 11 probably going to last longer than all of 12 us. 13 Q. Because it's made of plastic, 14 correct? 15 A. Correct. 16 Q. And when you're discussing 17 whether or not to have this implant, do 18 you describe the inflammatory response 19 with your patients as chronic, or would 20 you describe it as transient? 21 A. So, from what the patient is 22 going to realize, 'cause the chronic 23 inflammatory reaction is something that 24 the patients don't realize that there's a</p>	<p>Page 161</p> <p>1 with no gain. 2 Q. Have you, in fact, described the 3 mesh as like rebar in concrete? 4 A. Okay. So, what I was describing 5 is there, it's not like rebar in concrete. 6 What I was trying to show over there, and 7 you're going to pull out my picture, I got 8 it. What I was trying to describe there 9 is that the repair is a more durable type 10 of repair. 11 And that wasn't to patients, by 12 the way. That is meant to other 13 physicians. 14 But the repair there is for the 15 body to integrate into the mesh as the 16 concrete integrates into the rebar. 17 Q. Using your analogy, how easy is 18 it to remove rebar from concrete? 19 A. I have no clue. I've never done 20 that. 21 Q. And how easy is it to remove 22 mesh from the tissue once it's been 23 incorporated? 24 A. Removing the slings, if it's an</p>

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<p>1 exposure, I don't find is a terribly 2 difficult procedure, as I have mentioned 3 in my report already. The more mesh you 4 need to take out, the more procedure you 5 need to go ahead and do. But removing the 6 mesh, especially with sling mesh, you can 7 remove what you need to get out.</p> <p>8 Q. When you remove the mesh, do you 9 necessarily remove the tissue that it's 10 incorporated into?</p> <p>11 A. So, when I remove the mesh, I 12 try to not cut or damage any vital 13 structures. So usually what I will be 14 doing is cutting on the mesh itself in 15 order to remove the mesh once I get a free 16 end. I'm going to take my scissor or a 17 scalpel to try to shave off and shave out 18 the mesh and -- what was the question 19 again?</p> <p>20 Q. You lost me.</p> <p>21 If you're treating an erosion 22 into the bladder, for example, there's no 23 mesh sticking out visibly, correct?</p> <p>24 A. Correct.</p>	<p>1 this Power Point, Doctor?</p> <p>2 A. So, this was probably a talk or 3 a grand grounds that I gave at some point 4 in time in order to -- that I gave at some 5 point in time.</p> <p>6 Q. Would you have gotten paid to 7 give this talk?</p> <p>8 A. Not necessarily.</p> <p>9 Q. And on page I think it's 3.</p> <p>10 A. Okay.</p> <p>11 Q. On the bottom right corner you 12 have: "Mesh equals reinforced concrete." 13 Do you see that?</p> <p>14 A. Yes, I do.</p> <p>15 Q. And you have a picture with the 16 rebar on the left and then the concrete on 17 the right; is that correct?</p> <p>18 A. Yes, I do.</p> <p>19 Q. And that's the analogy you used 20 to describe the mesh here; is that fair?</p> <p>21 MR. ROSENBLATT: Object to form.</p> <p>22 A. Well, once again, my analogy 23 here is for integration and native tissue 24 repair relies on your own tissues to</p>
<p>1 Q. And when you remove the mesh, 2 you're going to cut out some tissue with 3 it, correct?</p> <p>4 A. A very small amount, yes.</p> <p>5 Q. Because it's been incorporated, 6 right?</p> <p>7 A. The tissue in the interstices, 8 or in the pores usually would come out.</p> <p>9 Q. Because it's been integrated 10 into the body, correct?</p> <p>11 A. Correct.</p> <p>12 Q. By design, correct?</p> <p>13 A. Correct.</p> <p>14 Q. I'm handing you what's been 15 marked as Exhibit 5.</p> <p>16 (Exhibit Winkler 5, Power Point 17 slide deck of Harvey Winkler, M.D., 18 was marked for identification, as of 19 this date.)</p> <p>20 BY MR. BENTLEY:</p> <p>21 Q. This is one of the Power Points 22 you provided to us prior to this 23 deposition.</p> <p>24 On page -- first of all, what is</p>	<p>1 support it.</p> <p>2 We know that tissue has wear and 3 tear on it, and the idea over here is that 4 we're going to get a more durable and 5 longer-lasting repair and have better 6 efficacy if we go ahead and use that.</p> <p>7 Q. If you go ahead and use?</p> <p>8 A. And use that synthetic mesh or 9 sling.</p> <p>10 Q. That acts like a rebar in 11 concrete?</p> <p>12 A. I didn't say it acts like a 13 rebar in concrete.</p> <p>14 I said the philosophy behind it 15 is that why is concrete stronger when you 16 put rebar into it? Because you've got 17 something that it sticks on to, right. So 18 the same philosophy here is when you're 19 going to put that mesh in, you've got your 20 tissue to stick onto.</p> <p>21 Q. It's an analogy you 22 appropriately used to describe the 23 integration of the mesh into tissue, 24 correct?</p>

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<p>1 A. Correct, but taking out the mesh 2 is not equivalent to chiseling away on 3 concrete.</p> <p>4 MR. BENTLEY: I'm going to hand 5 you what's marked as Exhibit 6, which 6 is another one of the Power Points 7 that you produced.</p> <p>8 (Exhibit 6, Power Point slide 9 deck of Harvey Winkler, M.D., was 10 marked for identification, as of this 11 date.)</p> <p>12 MR. BENTLEY: I'm going to hand 13 you what is marked as Exhibit 7, which 14 is another Power Point.</p> <p>15 (Exhibit Winkler 7, Power Point 16 slide deck of Harvey Winkler, M.D., 17 was marked for identification, as of 18 this date.)</p> <p>19 MR. BENTLEY: Here's Exhibit 8, 20 which is another Power Point you 21 produced.</p> <p>22 (Exhibit Winkler 8, Power Point 23 slide deck of Harvey Winkler, M.D., 24 was marked for identification, as of</p>	<p>1 THE WITNESS: Okay. 2 MR. BENTLEY: Exhibit 12 is 3 another Power Point. 4 (Exhibit Winkler 12, Power Point 5 slide deck of Harvey Winkler, M.D., 6 was marked for identification, as of 7 this date.)</p> <p>8 MR. BENTLEY: Exhibit 13 is 9 another Power Point. 10 (Exhibit Winkler 13, Power Point 11 slide deck of Harvey Winkler, M.D., 12 was marked for identification, as of 13 this date.)</p> <p>14 MR. BENTLEY: Exhibit 14, 15 another Power Point. 16 (Exhibit Winkler 14, Power Point 17 slide deck of Harvey Winkler, M.D., 18 was marked for identification, as of 19 this date.)</p> <p>20 THE WITNESS: Are we just going 21 through all of them?</p> <p>22 MR. BENTLEY: I'm just entering 23 them for the record before I forget. 24 Exhibit 15.</p>
<p>1 this date.)</p> <p>2 MR. BENTLEY: I'm going to hand 3 you Exhibit 9, which is another Power 4 Point.</p> <p>5 (Exhibit Winkler 9, Power Point 6 slide deck of Harvey Winkler, M.D., 7 was marked for identification, as of 8 this date.)</p> <p>9 MR. BENTLEY: I'm going to hand 10 you what is being marked as 11 Exhibit 10, another Power Point 12 produced.</p> <p>13 (Exhibit Winkler 10, Power Point 14 slide deck of Harvey Winkler, M.D., 15 was marked for identification, as of 16 this date.)</p> <p>17 MR. BENTLEY: Exhibit 11 is 18 another Power Point.</p> <p>19 (Exhibit Winkler 11, Power Point 20 slide deck of Harvey Winkler, M.D., 21 was marked for identification, as of 22 this date.)</p> <p>23 MR. BENTLEY: We can just set 24 these aside for now.</p>	<p>1 Page 167</p> <p>1 (Exhibit Winkler 15, Power Point 2 slide deck of Harvey Winkler, M.D., 3 was marked for identification, as of 4 this date.)</p> <p>5 MR. BENTLEY: 16.</p> <p>6 (Exhibit Winkler 16, Power Point 7 slide deck of Harvey Winkler, M.D., 8 was marked for identification, as of 9 this date.)</p> <p>10 MR. BENTLEY: 17.</p> <p>11 (Exhibit Winkler 17, Power Point 12 slide deck of Harvey Winkler, M.D., 13 was marked for identification, as of 14 this date.)</p> <p>15 MR. BENTLEY: 18.</p> <p>16 (Exhibit Winkler 18, Power Point 17 slide deck of Harvey Winkler, M.D., 18 was marked for identification, as of 19 this date.)</p> <p>20 (Exhibit Winkler 19, Power Point 21 slide deck of Harvey Winkler, M.D., 22 was marked for identification, as of 23 this date.)</p>

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<p>1 BY MR. BENTLEY:</p> <p>2 Q. Doctor, we've entered several</p> <p>3 Power Point presentations that you</p> <p>4 produced, and these Power Points, did you</p> <p>5 make these yourself, or someone in your</p> <p>6 office make them for you?</p> <p>7 A. The slides?</p> <p>8 Q. Yes.</p> <p>9 A. I made them most likely myself.</p> <p>10 I don't remember going -- some of them are</p> <p>11 going years back, if anyone helped me or</p> <p>12 where I got the information from, but</p> <p>13 generally I try to make my own slides.</p> <p>14 Sometimes I do them with the fellows</p> <p>15 today.</p> <p>16 Q. And these are all from</p> <p>17 presentations you gave?</p> <p>18 A. In the past, yeah.</p> <p>19 Q. Do you have any way to tell what</p> <p>20 dates these presentations were given on?</p> <p>21 A. Honestly, no.</p> <p>22 Q. If you could please turn to page</p> <p>23 42 of your report.</p> <p>24 A. Got it.</p>	<p>1 log; you don't track complications?</p> <p>2 A. Correct.</p> <p>3 Q. So when you say you have not</p> <p>4 seen any noticeable difference --</p> <p>5 A. But I will tell you I think my</p> <p>6 complication rate is low 'cause, once</p> <p>7 again, I'm not seeing that many patients</p> <p>8 back that I'm taking back to the operating</p> <p>9 room in order to treat for a complication.</p> <p>10 Q. Right. And my question is when</p> <p>11 you state in your report that you've not</p> <p>12 seen any noticeable difference in cure</p> <p>13 complications between the two meshes, is</p> <p>14 that simply based upon your review of the</p> <p>15 literature?</p> <p>16 A. So, it's based on what I've seen</p> <p>17 in my patient population 'cause I switched</p> <p>18 from one to the other. I didn't see a</p> <p>19 noticeable increase or decrease</p> <p>20 complication rate and what I've reviewed</p> <p>21 in the literature.</p> <p>22 And I've been using both for</p> <p>23 almost up 'til when AMS Astora went out of</p> <p>24 business because, if I remember correctly,</p>
<p style="text-align: center;">Page 171</p> <p>1 Q. You state: "I was an early</p> <p>2 adopter of TVT which has been available in</p> <p>3 mechanically-cut in the United States from</p> <p>4 '98 to present, and I also used TVT</p> <p>5 laser-cut mesh, in addition to TVT-Exact</p> <p>6 (only available in laser-cut), and have</p> <p>7 not seen any noticeable difference in</p> <p>8 objective cure, subjective cure, or</p> <p>9 complications including mesh exposures,</p> <p>10 pelvic pain and dyspareunia."</p> <p>11 Did I read that correct?</p> <p>12 A. Yes.</p> <p>13 Q. We've already discussed a little</p> <p>14 bit we don't have any reliable way to</p> <p>15 estimate how many of your patients had</p> <p>16 complications, correct?</p> <p>17 A. I have never -- I haven't done a</p> <p>18 systemic review. Once again, I think my</p> <p>19 complication rate is lower than the</p> <p>20 literature.</p> <p>21 However, I will tell patients</p> <p>22 when I talk to patients it's what's quoted</p> <p>23 in the literature.</p> <p>24 Q. Because you don't have a case</p>	<p>1 their transobturator sling is a</p> <p>2 mechanically-cut sling. So I was -- I've</p> <p>3 been using mechanically-cut slings for</p> <p>4 years.</p> <p>5 Q. And you don't cite to any study</p> <p>6 here that you don't have a difference</p> <p>7 between the --</p> <p>8 MR. BENTLEY: Strike that.</p> <p>9 Q. You don't cite to any study here</p> <p>10 indicating that TVT-R, machine-cut is the</p> <p>11 same as TVT laser-cut?</p> <p>12 A. Well, I have the Thubert study,</p> <p>13 right.</p> <p>14 Q. And the Thubert study looks at</p> <p>15 TVT-Exact, correct?</p> <p>16 A. Versus TVT.</p> <p>17 Q. Right, and we already discussed</p> <p>18 the TVT-Exact has different diameter</p> <p>19 trocars, correct?</p> <p>20 A. We have discussed that, yes.</p> <p>21 Q. And you don't cite any study</p> <p>22 specifically comparing TVT machine-cut to</p> <p>23 TVT laser-cut, correct?</p> <p>24 A. Yeah, but we're not -- the</p>

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<p>1 trocars are not the issue here with the 2 mechanical-cut and the laser-cut. 3 We're talking about the mesh, so 4 what difference what trocar is attached 5 to? 6 Q. What study do you have that 7 compares TVT-R machine-cut to TTVT-R 8 laser-cut? 9 A. In terms of the mesh itself, we 10 can look at the Thubert study. 11 Q. The Thubert study uses 12 TTVT-Exact, right? 13 A. Versus TTVT mechanical-cut. 14 Q. And my question is using TTVT 15 Retropubic machine-cut as compared to TTVT 16 laser-cut, what study compares those two 17 head to head? 18 A. I'm not aware of any study, but 19 once again, I'm not aware of what the 20 difference is on the mesh properties as 21 opposed to what needles you're putting in 22 to put them in there. 23 Q. On the Thubert study, you state 24 that it is TTVT versus TTVT-Exact, correct?</p>	<p>1 Retropubic was initially a clear mesh? 2 A. Yes. 3 Q. And subsequent, Ethicon 4 introduced a blue mesh that replaced the 5 clear mesh, correct? 6 A. Yes. 7 Q. When Ethicon introduced the blue 8 mesh for TTVT Retropubic, are you aware 9 that Ethicon received reports of blue 10 particles in unopened packaging? 11 A. I'm aware of that today, yes. 12 Q. When did you learn that? 13 A. I learned that on my review of 14 the documents that Ethicon had sent over 15 to me, but I had looked at these meshes 16 and seen these meshes and it's not 17 something that overly surprised me that a 18 particle may have been in there, 19 especially in thousands of them that they 20 produced. 21 Q. What if there was more than one 22 particle, that didn't concern you? 23 A. No, it didn't concern me. 24 Q. It doesn't concern you that</p>
<p style="text-align: center;">Page 175</p> <p>1 A. Yes. 2 Q. Do you know what percentage of 3 the TTVT cases in Thubert were machine-cut? 4 A. I don't recall, but I'd be glad 5 to look at that literature if you have it. 6 In addition, if you look at Lim 7 underneath that where they looked at 8 mechanically-cut TTVT slings to the 108 9 Advantage slings, the needles on Advantage 10 slings were almost identical, or the 11 trocars are almost identical to the TTVT-R 12 trocars. So there is some literature of 13 comparable type of procedures. 14 Q. Comparable, but it's not exactly 15 the TTVT-R, correct? 16 A. It's not the TTVT-R. 17 Q. Right. Doctor, you started 18 using -- 19 MR. BENTLEY: Strike that. 20 Q. You were trained on TTVT 21 Retropubic in Philadelphia around 1998 by 22 Dr. Vincent Lucente, correct? 23 A. Yes. 24 Q. And do you recall that TTVT</p>	<p style="text-align: center;">Page 177</p> <p>1 particles were falling off the mesh before 2 it was even implanted? 3 A. I don't care what happens with 4 the particles falling off the mesh 5 implanted. Once that mesh was implanted, 6 I don't believe that particles were 7 falling off, and I don't think it made any 8 difference clinically. 9 Q. What studies do you have to 10 support your opinion that the particle 11 loss stopped once it was implanted? 12 A. There's not going to be any 13 study on that. No one's going to go back 14 and look on it. But I don't have any 15 studies, that I'm aware of, whether it's 16 plaintiff studies or defense studies, that 17 actually show complete breakage of mesh 18 fibers in vivo. 19 Q. You don't have any studies to 20 support your opinion that the particle 21 loss stops after implantation. 22 Do you have any reason or 23 explanation of why you think that the 24 particle loss would stop after it's</p>

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<p>1 implanted?</p> <p>2 A. Once you get tissue integration</p> <p>3 and once -- unless -- once you get tissue</p> <p>4 integration around that mesh, why would I</p> <p>5 assume that a piece would suddenly tear</p> <p>6 off?</p> <p>7 When you hold the mesh and you</p> <p>8 put it down, it doesn't spontaneously come</p> <p>9 out. It's when you stretch it beyond its</p> <p>10 limits that it's intended to when I put it</p> <p>11 in surgically do we see that particle</p> <p>12 fray.</p> <p>13 Q. Well, you know that unopened</p> <p>14 packages before it was implanted, there's</p> <p>15 some particles that fell off, correct?</p> <p>16 A. I don't know if it fell off or</p> <p>17 if it fell off during the cutting. I</p> <p>18 don't know when it got into that box.</p> <p>19 Q. But it's your reason that you</p> <p>20 intend to offer to the jury that the</p> <p>21 particle loss stops once it's integrated;</p> <p>22 is that correct?</p> <p>23 A. I have no reason to believe that</p> <p>24 there are particles breaking off mesh once</p>	<p>1 A. I would just like to comment we</p> <p>2 never stretch it out 50 percent when we're</p> <p>3 putting it in a patient.</p> <p>4 Q. My question is in your report,</p> <p>5 you state that the mesh loses particles</p> <p>6 when it's elongated at 50 percent</p> <p>7 according to studies done by Ethicon that</p> <p>8 you cite in your report, correct?</p> <p>9 A. Correct, on page 45.</p> <p>10 Q. And it's your testimony that</p> <p>11 that's beyond the physiological range of</p> <p>12 elongation once implanted; is that</p> <p>13 correct?</p> <p>14 A. That's correct.</p> <p>15 Q. And then --</p> <p>16 A. In my opinion.</p> <p>17 Q. -- what's your opinion as to</p> <p>18 what the physiological range of elongation</p> <p>19 is once it's implanted?</p> <p>20 A. I don't believe -- I don't have</p> <p>21 a great answer for you of exactly how long</p> <p>22 these meshes -- how long -- if -- if these</p> <p>23 meshes do elongate when they're in the</p> <p>24 body or they do stretch. I would think if</p>
<p style="text-align: center;">Page 179</p> <p>1 it's in the patient's body.</p> <p>2 Q. And your explanation is because</p> <p>3 once it's integrated, it's not going to</p> <p>4 fall apart?</p> <p>5 A. Well, you have tissues</p> <p>6 supporting around it. So you have other</p> <p>7 tissue that's bearing load here as well.</p> <p>8 I have no indication that, and I</p> <p>9 do not believe that particles are</p> <p>10 mysteriously just breaking off.</p> <p>11 Q. If they were, would that be a</p> <p>12 problem?</p> <p>13 A. I don't think that would be a</p> <p>14 problem, to be honest with you. Unless</p> <p>15 they were clinically causing an issue for</p> <p>16 that patient.</p> <p>17 We've been putting in these</p> <p>18 sutures for the longest time and you have</p> <p>19 little particles of suture and generally</p> <p>20 it doesn't cause a problem.</p> <p>21 Q. Doctor, you say that mesh loses</p> <p>22 particles when it's elongated at the 50</p> <p>23 percent elongation, in your report I</p> <p>24 believe on page 55.</p>	<p style="text-align: center;">Page 181</p> <p>1 they were elongating or stretching at a</p> <p>2 considerable rate, we would see a</p> <p>3 significant decrease in efficacy as time</p> <p>4 went on.</p> <p>5 So, based on my clinical</p> <p>6 opinion, I do not have experience in these</p> <p>7 meshes -- in the midurethral sling meshes</p> <p>8 significantly elongating.</p> <p>9 Q. In any of the plaintiff reports</p> <p>10 that you read, did you notice any of the</p> <p>11 evidence they cited discussing the</p> <p>12 physiological range of elongation of the</p> <p>13 mesh once implanted?</p> <p>14 A. I have not seen any clinical</p> <p>15 data of how long these meshes are</p> <p>16 elongating. There's theoretical data of</p> <p>17 how they will react, but I do not have any</p> <p>18 solid clinical data to support any of</p> <p>19 that.</p> <p>20 Q. I'm just trying to understand on</p> <p>21 page 45 you put you've seen the Ethicon</p> <p>22 Power Point relied upon by plaintiff's</p> <p>23 experts comparing the physical differences</p> <p>24 to TTV mechanical and laser-cut, and you</p>

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<p>1 put: "When stretched beyond the 2 physiological range at 50 percent 3 elongation."</p> <p>4 What's your basis that that's 5 beyond the physiological range?</p> <p>6 A. So, that's going to be doubling 7 the length of the sling. So, when I go in 8 and if I have to do a mesh exposure or a 9 mesh erosion or a tightening of the sling, 10 I do not see stretching of that.</p> <p>11 THE WITNESS: And Paul, do we 12 have that picture of a sling that 13 eroded?</p> <p>14 A. There's a picture of a -- this 15 is a -- this is it.</p> <p>16 MR. ROSENBLATT: (Handing.) 17 (Exhibit Winkler 25, color copy 18 of photograph, was marked for 19 identification, as of this date.)</p> <p>20 BY MR. BENTLEY:</p> <p>21 Q. Doctor, I marked what is labeled 22 as Exhibit 25, which is a picture you 23 brought to the deposition.</p> <p>24 And could you describe what this</p>	<p>1 believe that that mesh was incorrectly 2 implanted by the implanting physician? 3 A. I would find it hard to believe 4 that an implanting physician would leave a 5 piece of mesh like that when he's 6 implanting it.</p> <p>7 Q. And the mesh exposure could 8 develop postoperatively, correct?</p> <p>9 A. Correct.</p> <p>10 Q. And that could develop even if 11 the implanting physician put it in without 12 tension, as you do, correct?</p> <p>13 A. We have agreed that that's a 14 commonly known complication.</p> <p>15 Q. That can happen even if it's 16 implanted correctly, correct?</p> <p>17 A. It can happen, yes.</p> <p>18 Q. And we were discussing particle 19 loss previously.</p> <p>20 Do you remember that?</p> <p>21 A. I do.</p> <p>22 Q. And you wanted to discuss this 23 picture in response to some of our 24 questioning about particle loss.</p>
<p>1 is a picture of?</p> <p>2 A. This is a mesh exposure of what 3 I think is a TVT sling, and we can see in 4 this picture there's an exposure of the 5 mesh into the vagina. And on exposures 6 either I would see something commonly like 7 this or -- and I don't see significant 8 elongation in opening of these meshes and 9 significant stretching of these meshes 10 when I remove them. So there's no reason 11 for me to believe that these meshes 12 elongate up to 50 percent of their length.</p> <p>13 Q. Let's talk about that a little 14 bit.</p> <p>15 It's a picture of an exposure 16 which, by your definition, that's a 17 externally visible piece of the mesh, 18 correct?</p> <p>19 A. Correct.</p> <p>20 Q. And looking at this picture, do 21 you have any way to determine what caused 22 that mesh exposure?</p> <p>23 A. No, I do not.</p> <p>24 Q. Do you have any reason to</p>	<p>1 Do you remember that?</p> <p>2 A. Yeah, I want to discuss this 3 picture in response to elongation.</p> <p>4 Q. Okay, thank you.</p> <p>5 So, it's your testimony that 6 because this picture doesn't show 7 elongation, particle loss doesn't happen? 8 I'm trying to -- can you help 9 me?</p> <p>10 A. No. You asked me how do you 11 know that elongation in the body does not 12 happen above 50 percent. So I'm trying to 13 give you an example of how I base that 14 opinion on.</p> <p>15 Q. So, if there was elongation, 16 would you expect to see the mesh maybe 17 roped?</p> <p>18 A. I've never seen roping of the 19 TVT mesh, and I know that people have 20 described that.</p> <p>21 What I usually -- if the mesh 22 gets a little -- can get a little too 23 tight, we're not going to see this kind of 24 a picture. We're going to see more of</p>

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<p>1 that voiding dysfunction or difficulty 2 urinating picture. 3 So, the interstices and pores 4 are still there. It's just, yes, it does 5 get a little, I don't want to use the word 6 "roping." It can get tight you are under 7 the urethra because it's scarring too 8 much.</p> <p>9 Q. But mesh can rope, you've read 10 about that, right?</p> <p>11 A. I've read about that, right.</p> <p>12 Q. You don't have any reason to 13 disbelieve people that have seen roped 14 mesh, do you?</p> <p>15 A. I don't have any disbelief in 16 that.</p> <p>17 My opinion is that when you get 18 that roping, there may have been too much 19 tension applied on the implanting portion 20 of the procedure as opposed to all of a 21 sudden the mesh roping upon itself.</p> <p>22 Q. Have you seen bunched mesh in 23 your clinical experience?</p> <p>24 A. Yes, I have. And there are</p>	<p>1 in for prolapse.</p> <p>2 Q. When you're implanting mesh, if 3 the stiffness of the mesh is different, 4 does that affect the level of tension that 5 is set during the implant?</p> <p>6 MR. ROSENBLATT: Object to form.</p> <p>7 MR. BENTLEY: That was awful.</p> <p>8 BY MR. BENTLEY:</p> <p>9 Q. If a physician is -- if you 10 yourself are implanting a mesh and you've 11 developed a technique to implant it such 12 that there's minimal tension put on it, 13 correct, and that's your intended goal 14 when you're implanting the mesh is to have 15 tension-free, correct?</p> <p>16 A. Correct.</p> <p>17 Q. If the mesh is stiffer than what 18 you've been accustomed to, does it change 19 how you have to set the tension of that 20 mesh?</p> <p>21 A. I don't know how to answer that 22 question, to be honest with you.</p> <p>23 Q. If you have a mesh that's 24 stiffer than the one you've trained on</p>
<p style="text-align: center;">Page 187</p> <p>1 reports of mesh moving and migration and 2 retracting. Nothing -- you can't a 3 hundred percent guarantee that anything's 4 going to stay in the place that you put it 5 in.</p> <p>6 MR. ROSENBLATT: I wasn't able 7 to get my objection in in time. I 8 don't know if you're asking about SUI 9 or POP.</p> <p>10 MR. BENTLEY: Sure.</p> <p>11 BY MR. BENTLEY:</p> <p>12 Q. Have you seen reports of mesh 13 that's been implanted to treat 14 incontinence of the mesh being roped?</p> <p>15 MR. ROSENBLATT: Object to form.</p> <p>16 A. I have not seen roping occur 17 with a sling mesh.</p> <p>18 Q. Have you read reports or 19 literature that discusses TVT mesh that's 20 roped after implantation?</p> <p>21 A. I've read literature. I can't 22 say a hundred percent if that literature 23 was based on a midurethral sling or if 24 that literature was based on meshes placed</p>	<p style="text-align: center;">Page 189</p> <p>1 that you're accustomed to, does that need 2 to change the forces to be applied during 3 implantation?</p> <p>4 A. Once again, I don't know the 5 answer to that question.</p> <p>6 I would have to see the product, 7 look at it. I would do a cadaver lab on 8 the product. I would like to see data on 9 the product before I went ahead and 10 implanted it at this point in time.</p> <p>11 Q. Do you have an opinion as to 12 whether the stiffness of the mesh has any 13 clinical significance?</p> <p>14 MR. ROSENBLATT: Object to the 15 form.</p> <p>16 A. I don't know how to answer that 17 question in terms of if we're talking 18 about sling meshes, POP meshes. And even 19 if you probably then separate them out, I 20 wouldn't know how to answer that question 21 for you.</p> <p>22 Q. With respect to slings that are 23 implanted to treat incontinence, do you 24 have any opinion as to whether a stiffer</p>

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<p>1 mesh has clinical significance?</p> <p>2 A. Well, a stiffer mesh, it's</p> <p>3 stiffer for a reason. So why don't we</p> <p>4 break it down into what the reason is?</p> <p>5 Q. Yeah, I'm just trying to get an</p> <p>6 answer to that specifically, and then</p> <p>7 we'll break it down from there.</p> <p>8 Do you have any opinion as to</p> <p>9 whether or not a polypropylene sling mesh</p> <p>10 that's implanted to treat incontinence, if</p> <p>11 the mesh is stiffer, does it have a</p> <p>12 clinical significance for the patient?</p> <p>13 MR. ROSENBLATT: Object to form.</p> <p>14 A. Once again, I really don't know</p> <p>15 how to answer that question for you.</p> <p>16 MR. ROSENBLATT: What do you</p> <p>17 mean by "stiffer"? Maybe that might</p> <p>18 help.</p> <p>19 MR. BENTLEY: Well, it's the</p> <p>20 words -- well, we'll get to it.</p> <p>21 BY MR. BENTLEY:</p> <p>22 Q. Do you want to turn to page 44</p> <p>23 in your report?</p> <p>24 A. Sure.</p>	<p>1 they suggested.</p> <p>2 Do I think that that's going to</p> <p>3 happen with a TVT? No. The implantation</p> <p>4 of a TVT Secur, entirely different than</p> <p>5 any type of the slings than what we're</p> <p>6 talking about right now.</p> <p>7 Q. As you sit here today, do you</p> <p>8 have any criticism or critique of the</p> <p>9 Neuman 2011 study?</p> <p>10 A. I mean, I think we're comparing</p> <p>11 Secure to TVT-O. I was not a big Secur</p> <p>12 user, as we discussed in the past. So, if</p> <p>13 we want to go through criticism</p> <p>14 particularly, we're going to need to pull</p> <p>15 out that study, 'cause once again, I don't</p> <p>16 remember it word for word.</p> <p>17 Q. So you don't think that Neuman</p> <p>18 is really relative to the discussion of</p> <p>19 whether or not a stiffer mesh can cause</p> <p>20 clinical implications for the patient?</p> <p>21 A. Well, especially if we're going</p> <p>22 to talk about TVT Secur and TVT-O, a</p> <p>23 transobturator sling, in my opinion, is</p> <p>24 going to have a slightly higher</p>
<p>1 Q. You state: "Neuman 2011</p> <p>2 suggested that the stiffer TVT Secur</p> <p>3 laser-cut might have caused the de novo</p> <p>4 dyspareunia."</p> <p>5 Do you see that?</p> <p>6 A. Yes, I do.</p> <p>7 Q. Okay. So what do you mean by</p> <p>8 "stiffer mesh"?</p> <p>9 A. So, the laser-cut made it a</p> <p>10 little less, quote/unquote, stretchy at</p> <p>11 that point in time, in my opinion. And I</p> <p>12 did not think that that stretchiness made</p> <p>13 a difference from when I implanted the</p> <p>14 slings for TVT. If you are going to give</p> <p>15 me another sling, I'd have to see why it's</p> <p>16 stiffer.</p> <p>17 Q. So, here you cite a study that</p> <p>18 suggests that the stiffness might have</p> <p>19 actually caused de novo dyspareunia; is</p> <p>20 that correct?</p> <p>21 A. And that's with TVT Secur, which</p> <p>22 once again is an entirely different</p> <p>23 procedure, and placement for that is</p> <p>24 entirely different. So I will cite what</p>	<p>1 Page 191</p> <p>1 dyspareunia rate risk than a retropubic</p> <p>2 sling.</p> <p>3 Q. And I guess my question is then</p> <p>4 why do you include this in your TVT</p> <p>5 report?</p> <p>6 A. It was literature that I found.</p> <p>7 I didn't want to not include it at that</p> <p>8 point in time.</p> <p>9 Q. In your report, you don't</p> <p>10 provide any analysis of why you discount</p> <p>11 the study, correct?</p> <p>12 A. There's nothing more in my</p> <p>13 report about this, yes.</p> <p>14 Q. And as you sit here today, you</p> <p>15 don't have any analysis as to why you</p> <p>16 discount this study, do you?</p> <p>17 MR. ROSENBLATT: Object to form.</p> <p>18 If you want to pull it out, he</p> <p>19 could provide his criticisms of it.</p> <p>20 A. Yeah, I mean, once again I said</p> <p>21 that before. If we want to criticize, I</p> <p>22 can remember what I wrote. I can't</p> <p>23 remember what's in the paper.</p> <p>24 Q. And I can only read what you</p>

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<p>1 wrote, right?</p> <p>2 A. Right.</p> <p>3 So, I'm not saying that -- that</p> <p>4 it's proven. It's suggested and we're not</p> <p>5 going to hide that.</p> <p>6 Q. Do you disagree with their</p> <p>7 suggestion?</p> <p>8 A. With their suggestion?</p> <p>9 Q. Do you disagree with Neuman's</p> <p>10 suggestion that stiffer mesh might have</p> <p>11 caused de novo dyspareunia?</p> <p>12 A. Once again, I will not comment.</p> <p>13 I am not a Secur expert whatsoever. I am</p> <p>14 not a TVT-O expert whatsoever. So I don't</p> <p>15 think my -- I'm an expert on</p> <p>16 transobturator sling, but on the TVT-O</p> <p>17 device, I never used that. So I would</p> <p>18 refrain from giving an expert opinion on</p> <p>19 either of these two products.</p> <p>20 Q. So you're an expert on TVT</p> <p>21 Retropubic classic machine-cut; is that</p> <p>22 fair?</p> <p>23 A. So, I'm an expert on these</p> <p>24 slings. I'm not an expert on putting in</p>	<p>1 refrain from offering an expert opinion</p> <p>2 particularly on TVT-O.</p> <p>3 Q. And in your TVT and TVT-Exact</p> <p>4 report, you discuss the Neuman study,</p> <p>5 correct?</p> <p>6 A. Yeah.</p> <p>7 Do you mind getting the study?</p> <p>8 Q. And in your report, you note</p> <p>9 that they suggested that a stiffer mesh</p> <p>10 might have caused de novo dyspareunia; is</p> <p>11 that correct? Is that in your report?</p> <p>12 A. Correct.</p> <p>13 Q. As you sit here today, do you</p> <p>14 have any study or evidence to indicate</p> <p>15 that a stiffer mesh doesn't cause de novo</p> <p>16 dyspareunia?</p> <p>17 A. I don't have evidence that a</p> <p>18 stiffer mesh causes more or less de novo</p> <p>19 dyspareunia.</p> <p>20 They're suggesting it, and this</p> <p>21 is one study, in, let's see, how many</p> <p>22 people again?</p> <p>23 Q. The question, do you have any</p> <p>24 evidence that indicates contrary to what</p>
<p>1 the TVT-O.</p> <p>2 MR. ROSENBLATT: That's not a</p> <p>3 requirement for your expert, sir?</p> <p>4 Strike that.</p> <p>5 BY MR. BENTLEY:</p> <p>6 Q. I'm trying to figure out --</p> <p>7 A. I never put a TVT-O in. So</p> <p>8 how -- I don't want to really comment on</p> <p>9 the procedure.</p> <p>10 Q. And you wouldn't want to comment</p> <p>11 on the safety profile of the TVT-O,</p> <p>12 correct?</p> <p>13 A. I think the TVT-O is a safe</p> <p>14 procedure. I didn't say that it's not a</p> <p>15 safe procedure.</p> <p>16 I just said I would reserve</p> <p>17 offering an expert opinion on placing it</p> <p>18 and anything with dyspareunia.</p> <p>19 Q. Right.</p> <p>20 A. I'm an expert on the</p> <p>21 complications of the TVT-O. I'm an expert</p> <p>22 on what's in the literature on the TVT-O.</p> <p>23 I'm an expert on how to implant the TVT-O,</p> <p>24 but since I have never done it, I would</p>	<p>1 you cite in your report, do you have any</p> <p>2 evidence suggesting that, contrary to</p> <p>3 Neuman, that stiffer mesh does not cause</p> <p>4 de novo dyspareunia?</p> <p>5 A. I didn't say that a stiffer mesh</p> <p>6 is. The TVT Secur stiffer mesh.</p> <p>7 So, how do you know it's the</p> <p>8 mesh and not the implantation technique?</p> <p>9 Q. Doctor, my question is very</p> <p>10 precise.</p> <p>11 Do you have any evidence as you</p> <p>12 sit here today that a stiffer mesh does</p> <p>13 not cause de novo dyspareunia?</p> <p>14 A. I don't have any evidence that</p> <p>15 it causes more or less de novo</p> <p>16 dyspareunia.</p> <p>17 I have one study that you just</p> <p>18 pointed at of 79 patients in a different</p> <p>19 type of procedure than we're discussing</p> <p>20 today that may suggest it.</p> <p>21 Q. Doctor, do you hold yourself out</p> <p>22 as an expert on FDA regulations?</p> <p>23 A. I am an expert on FDA</p> <p>24 regulations when it comes to devices and</p>

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<p>1 implants for incontinence as well as for 2 the pelvic floor, in my opinion. 3 Q. Do you consider yourself an 4 expert regarding FDA requirements for 5 product labeling? 6 A. I'm aware of what's required in 7 the -- I am aware of what's required in 8 product labeling for devices, yes. 9 Q. What's required in product 10 labeling? 11 A. So, any type of -- first of all, 12 you need to explain the indication for 13 what should be in the product label. You 14 should try to explain who the device 15 should not be implanted in, and then you 16 would try to describe adverse events or 17 complications that are specific to the 18 device when used in that procedure the 19 device is indicated for. 20 Q. And what's your basis for that 21 definition? 22 A. I have read the, I think, the 23 CFR, CFR Rule 21. 24 Q. The entire chapter?</p>	<p>1 surgical management to each and every 2 unique patient." 3 Do you see that? 4 A. Yes, I do. 5 Q. What's your basis for that 6 opinion? 7 A. I don't rely on IFUs, nor should 8 any surgeon rely on an IFU on how to do a 9 surgical procedure. I don't rely on a 10 company to teach me the surgical procedure 11 in its entirety. I don't rely on an IFU 12 to teach me that procedure. Nor do I rely 13 on an IFU to tell me the commonly known 14 complications of a procedure. 15 Q. So, your basis for that opinion 16 is your personal experience and your 17 personal practice with regards to IFUs? 18 A. Well, it's my personal practice. 19 It's my discussion with other doctors. 20 There was a recent abstract that 21 shows that, was it Frommer, she's in 22 Hackensack. I can't recall the name. 23 That actually shows that up to 40 percent 24 of doctors don't even read IFUs.</p>
<p>1 A. No, I skimmed it. I'm not going 2 to remember it word for word. 3 Q. How did you decide which 4 sections to skim? 5 A. I don't recall how I decided 6 which ones I thought were more pertinent 7 to others. 8 Q. Did you review the 21 -- did you 9 skim the 21 CFR in preparation for this 10 report? 11 A. Yes, I did. 12 Q. In your report, you discuss the 13 IFU. Let's turn to page 22. 14 As we discussed, throughout your 15 report you include a number of citations 16 to footnotes; is that correct? 17 A. That's correct. 18 Q. And on page 22, you have a 19 paragraph that begins "Furthermore." 20 Do you see that? 21 A. Yes. 22 Q. And the second to last sentence 23 you put: "An IFU must give surgeons the 24 ability to individualize the procedure and</p>	<p>1 Q. Okay. But as you sit here 2 today, you can't tell me one of the CFR 3 sections that you skimmed that supports 4 your opinion; is that correct? 5 A. Can you show me the CFR? 6 MR. ROSENBLATT: Object to form. 7 That mischaracterizes. 8 BY MR. BENTLEY: 9 Q. Doctor, what CFR section 10 supports your opinion that an IFU must 11 give surgeons the ability to individualize 12 the procedure and surgical management to 13 each and every unique patient? 14 A. I don't recall by heart. 15 Can we see the CFR? 16 Q. You don't know it and it's not 17 in your report; is that fair? 18 A. I didn't say that. 19 MR. ROSENBLATT: Can I show him 20 his reliance list? 21 MR. BENTLEY: Please. 22 A. But I'm not going to remember 23 the report. 24 What I will tell you is --</p>

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<p>1 MR. BENTLEY: Actually, counsel, 2 he's got the reliance list right in 3 front of him.</p> <p>4 A. What I will tell you is the way 5 that we train doctors and the way we learn 6 is throughout medical school, throughout 7 residency and throughout fellowship, there 8 are certain basic requirements that we 9 need to teach. We teach our residents, 10 our fellows to individualize the surgical 11 procedure for the patient. We don't pick 12 a procedure and then find the right 13 patient for them. We teach them the 14 risks, the benefits, the contraindications 15 of specific procedures, and we also teach 16 them the adverse reaction to the surgical 17 procedures that we do. So we don't use an 18 IFU to teach us how to do surgery.</p> <p>19 Q. For your reference, Doctor, you 20 have your reliance list in front of you. 21 It's Exhibit 4.</p> <p>22 A. Yes.</p> <p>23 Q. And that Exhibit 4 is your 24 reliance list that you reviewed in</p>	<p>1 A. That's what I put in the 2 reliance list.</p> <p>3 Once again, I need to see 109(c) 4 to definitely confirm that.</p> <p>5 Q. Do you have any training in 6 interpreting federal regulations?</p> <p>7 A. I have training in using 8 devices. I've had training in developing 9 devices. I've had consulting train -- 10 I've done consulting work with -- with 11 industry in order to do device 12 improvements, device development, new 13 devices. I have written and signed off on 14 clinical evaluation report. I have been 15 teaching on IFU complications what are 16 commonly known and what are specific to 17 devices throughout my entire career.</p> <p>18 Q. My question was specific to the 19 federal regulations that govern labeling.</p> <p>20 A. I'm not --</p> <p>21 Q. Have you had any training 22 regarding the federal regulations 21 CFR 23 801?</p> <p>24 MR. ROSENBLATT: Object to form.</p>
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<p>1 preparation of this report?</p> <p>2 A. Yes.</p> <p>3 Q. On page 2 the top there's a CFR 4 cited.</p> <p>5 A. Yes, I do.</p> <p>6 Q. Is that your basis for this 7 opinion regarding what the requirements of 8 the IFU are?</p> <p>9 A. I don't remember -- that's the 10 reclassification for surgical mesh. That 11 is not what the requirement of what needs 12 to be in a IFU.</p> <p>13 Q. Okay.</p> <p>14 A. Is it?</p> <p>15 Q. So, I believe the next CFR 16 reference you have in here is the third or 17 fourth last page and at the top it's got 18 July 25th. I can tell you it's the fourth 19 from the back.</p> <p>20 A. 21 CFR 801?</p> <p>21 Q. 109 subsection C.</p> <p>22 A. Yes.</p> <p>23 Q. Is that your basis for the 24 opinion in your report?</p>	<p>1 A. We discuss -- we have had 2 training in terms of complications from 3 surgical procedures. It is not the -- we 4 don't -- we are concerned, and the doctors 5 are concerned of the common complications 6 and we want to teach those as opposed to 7 regardless of what the government 8 regulations are of what needs to be 9 included or what does not need to be 10 included, we want to teach what the 11 complications, adverse events are, 12 regardless if the government requires it 13 or not.</p> <p>14 Q. Do you consult with companies 15 regarding compliance with federal 16 regulations?</p> <p>17 A. I have been to the FDA and have 18 consulted with a company regarding 522 19 study and some regulations regarding that.</p> <p>20 Q. What's a 522 study?</p> <p>21 A. So, a 522 is a post-market study 22 ordered by the FDA on devices.</p> <p>23 Q. When are those ordered?</p> <p>24 A. Usually they're ordered after a</p>

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<p>1 device has been on the market. 2 Q. In what situations are 522 3 orders requested? 4 A. It's when the FDA decides that 5 they need more information on a device, 6 it's my understanding. 7 Q. If you could please turn to page 8 40 in your report. 9 A. Okay. 10 Q. The bottom paragraph you wrote: 11 "The TTVT IFU appropriately warned surgeons 12 of the potential adverse reactions 13 specific to the device, including damage 14 to vessels, nerves, bladder, urethra or 15 bowel, as well as the possibility of 16 extrusion, erosion, fistula formation or 17 inflammation." 18 And my question is your opinion 19 that the TTVT IFU appropriately warns, is 20 that based upon your experience as a 21 physician or your interpretation of a 22 specific federal regulation governing 23 labeling? 24 A. It's my interpretation of the</p>	<p>1 with any kind of surgery that you have 2 anywhere in your body, develop chronic 3 pain at that site. 4 MR. ROSENBLATT: And I don't 5 mean to interject on the record, but 6 to the extent Judge Goodwin does not 7 allow FDA testimony at trial, we would 8 not be offering him as an expert on 9 FDA regulations, but for purposes of 10 explaining his opinion, we'll offer 11 him. 12 BY MR. BENTLEY: 13 Q. And your basis for saying the 14 TTVT IFU appropriately warns is based upon 15 your review of the applicable 21 CFR 801, 16 correct? 17 A. It's based on my review of 18 multiple -- of my knowledge of the 19 procedure. It's based on my knowledge of 20 how we train our residents and what we 21 inform our residents. It's based on my 22 knowledge of continuing certification for 23 our doctors at this point in time, and 24 it's based on my reliance that device</p>
<p>1 CFR that says you do not need to include 2 commonly known adverse events. 3 Q. And which CFR is that again? 4 A. You have to remember -- it's CFR 5 21. I don't remember the exact number. 6 Q. So, it's your testimony and your 7 opinion that you intend to offer at trial 8 that Ethicon's IFU was in compliance with 9 the applicable 21 CFR 801 in governing 10 product labeling? That's your opinion? 11 A. That's my understanding, yes. 12 Q. And that's what you seek to 13 testify to at trial regarding your 14 opinions, that the TTVT IFU appropriately 15 warns? 16 A. There's nothing in that IFU that 17 I don't think I knew beforehand that's 18 specific to the TTVT device except for the 19 exposure or erosion with a synthetic mesh. 20 Some of the stuff -- some of the 21 commonly known chronic pelvic pain or 22 dyspareunia can happen with any surgery. 23 It can happen with any particular type of 24 vaginal surgery we do, and it can happen</p>	<p>1 companies do not and should not be 2 teaching surgeons on how to operate and 3 who -- and who are not the right patients 4 on it. They can give their opinions, but 5 it's ultimately the surgeon's decision. 6 Q. Okay. So, your standard for 7 what an appropriate IFU warning is, is 8 that based upon your review of the federal 9 regulations, or is that just your personal 10 opinion? 11 MR. ROSENBLATT: Object to the 12 form. 13 I think he just explained that 14 it's both his -- 15 MR. BENTLEY: I'm more confused 16 now than I was to start. 17 THE WITNESS: I'm sorry. 18 BY MR. BENTLEY: 19 Q. Is your opinion that the TTVT IFU 20 appropriately warns, is that opinion based 21 on your review of federal regulations, or 22 is that based upon your personal opinion 23 as a physician? 24 MR. ROSENBLATT: Object to form;</p>
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<p>1 asked and answered.</p> <p>2 A. It's based on both. It's based 3 on my review, as well as the way in my 4 clinical experience and my teaching 5 experience we have trained our fellows, trained 6 other medical students, trained 7 our residents. I may discuss 8 complications that aren't in an IFU with a 9 medical student, resident or fellow based 10 on specific to the surgical procedure that 11 we're performing.</p> <p>12 Q. Have you reviewed any guidance 13 documents that the FDA has put out 14 regarding their interpretation of the 15 labeling statutes?</p> <p>16 A. I think I have.</p> <p>17 Can we show what we're talking 18 about?</p> <p>19 Q. Well, first do you know guidance 20 documents are put out by the FDA?</p> <p>21 A. Yeah, I went on the FDA 22 Web site. I've seen some of the stuff. 23 I've done some searches.</p> <p>24 Q. And in interpreting FDA</p>	<p>1 ruling.</p> <p>2 Q. You can interpret it contrary to 3 what the FDA guidance document would put 4 out?</p> <p>5 A. No, what the FDA rule says is 6 what I need to follow.</p> <p>7 Q. So you could just discount their 8 guidance?</p> <p>9 A. You can't discount their 10 guidance. But I don't -- I'm not a 11 lawyer, so, but I need to follow the rule 12 and I need to -- the guidance can guide me 13 on how to follow their rules.</p> <p>14 Q. So, your opinion is that the IFU 15 is adequate because it lists --</p> <p>16 MR. BENTLEY: Let me rephrase 17 that.</p> <p>18 BY MR. BENTLEY:</p> <p>19 Q. You think the IFU is appropriate 20 because a lot of these complications are 21 commonly known; is that fair?</p> <p>22 A. They're commonly known to the 23 physicians, yes, performing these 24 procedures.</p>
<p>1 regulations, it's important to review 2 their guidance on how to interpret it, 3 right?</p> <p>4 A. If you're going to be writing an 5 IFU, I think it's important to review the 6 regulations.</p> <p>7 Q. Including the guidance documents 8 put out by the FDA?</p> <p>9 A. I would try to review all 10 documents if I was doing that.</p> <p>11 Q. And to reach an opinion 12 regarding the adequacy of the warnings 13 that are required per federal regulations, 14 it's important to review the guidance 15 documents that are put out by the FDA, 16 right?</p> <p>17 MR. ROSENBLATT: Object to form; 18 mischaracterization that a guidance 19 documents equals what are required.</p> <p>20 MR. BENTLEY: That's fair.</p> <p>21 BY MR. BENTLEY:</p> <p>22 Q. You can answer.</p> <p>23 A. I would review the official 24 rule, and I can interpret it as per the</p>	<p>1 regulations, it's important to review 2 their guidance on how to interpret it, 3 right?</p> <p>4 A. If you're going to be writing an 5 IFU, I think it's important to review the 6 regulations.</p> <p>7 Q. Including the guidance documents 8 put out by the FDA?</p> <p>9 A. I would try to review all 10 documents if I was doing that.</p> <p>11 Q. And to reach an opinion 12 regarding the adequacy of the warnings 13 that are required per federal regulations, 14 it's important to review the guidance 15 documents that are put out by the FDA, 16 right?</p> <p>17 MR. ROSENBLATT: Object to form; 18 mischaracterization that a guidance 19 documents equals what are required.</p> <p>20 MR. BENTLEY: That's fair.</p> <p>21 BY MR. BENTLEY:</p> <p>22 Q. You can answer.</p> <p>23 A. I would review the official 24 rule, and I can interpret it as per the</p>

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<p>1 appropriately warns, correct?</p> <p>2 A. I've answered that.</p> <p>3 Yes, correct.</p> <p>4 Q. And you don't in your report</p> <p>5 discuss whether or not you have to warn</p> <p>6 about the severity or likelihood; is that</p> <p>7 correct?</p> <p>8 A. I report what the complications</p> <p>9 are. I'm not aware of any numbers that</p> <p>10 need to be reported.</p> <p>11 Q. Well, for example, death is a</p> <p>12 potential complication of any surgery;</p> <p>13 isn't that correct?</p> <p>14 A. That's correct.</p> <p>15 Q. But it's highly unlikely with</p> <p>16 most surgeries, correct?</p> <p>17 A. Correct.</p> <p>18 Q. But if death was actually more</p> <p>19 likely with one procedure compared to</p> <p>20 other ones, that would be important</p> <p>21 information to be in a label, wouldn't it?</p> <p>22 MR. ROSENBLATT: Object to form.</p> <p>23 A. I mean, death is a really</p> <p>24 serious complication that we're discussing</p>	<p>1 a complication actually has an increased</p> <p>2 frequency with one product compared to</p> <p>3 another one, assuming that, do you</p> <p>4 understand that manufacturers of products</p> <p>5 have an obligation to actually share that</p> <p>6 frequency information with people?</p> <p>7 MR. ROSENBLATT: Object to form.</p> <p>8 A. I got to be honest, I don't</p> <p>9 understand the question.</p> <p>10 Q. Right.</p> <p>11 A. It's long.</p> <p>12 Q. If you had reviewed the guidance</p> <p>13 documents, would you include them in your</p> <p>14 reliance list?</p> <p>15 A. If I remembered to, yes, I would</p> <p>16 have included it.</p> <p>17 Q. In your report you state:</p> <p>18 "There's no overt need to describe the</p> <p>19 possibility of chronic pelvic pain or</p> <p>20 dyspareunia because, as stated previously,</p> <p>21 their inherent risk to surgery, and</p> <p>22 vaginal surgery in particular, which are</p> <p>23 commonly known."</p> <p>24 What's your basis for opining</p>
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<p>1 here at this point in time. So, I think</p> <p>2 intuitively every patient knows that</p> <p>3 complications can occur, and death can</p> <p>4 occur with any surgery or any point in</p> <p>5 time, unfortunately.</p> <p>6 Q. Okay. And if death, which can</p> <p>7 occur with any surgery, if the occurrence</p> <p>8 was more frequent with one product, do you</p> <p>9 understand that the manufacturer would</p> <p>10 have an obligation to warn about the</p> <p>11 increased frequency of that hazard?</p> <p>12 MR. ROSENBLATT: Object to form.</p> <p>13 What do you mean by "more</p> <p>14 frequent"?</p> <p>15 A. And I don't -- are you talking</p> <p>16 about a procedure? Are you talking about</p> <p>17 a product? I'm not aware of --</p> <p>18 Q. We're talking about products and</p> <p>19 your opinions in the report that they</p> <p>20 appropriately warn in the IFU.</p> <p>21 And you're saying that these</p> <p>22 complications are commonly known, correct?</p> <p>23 A. Correct.</p> <p>24 Q. If it's not commonly known that</p>	<p>1 that the labels are adequate if there's an</p> <p>2 increased frequency that people are not</p> <p>3 commonly aware of?</p> <p>4 MR. ROSENBLATT: Object to form.</p> <p>5 A. I think anyone doing these</p> <p>6 procedures knows that chronic pain or</p> <p>7 dyspareunia can happen. Anything in the</p> <p>8 vagina, anything that we -- any kind of</p> <p>9 surgery that we do can cause the</p> <p>10 possibility of dyspareunia and chronic</p> <p>11 pelvic pain can happen with any particular</p> <p>12 surgery.</p> <p>13 Q. So it's your opinion that the</p> <p>14 IFU doesn't need to warn about anything?</p> <p>15 MR. ROSENBLATT: Object to form;</p> <p>16 mischaracterization.</p> <p>17 A. The IFU should warn, in my</p> <p>18 opinion, IFUs should warn about adverse</p> <p>19 events specific and unique to that</p> <p>20 product, not necessarily the procedure.</p> <p>21 Q. And what are the adverse</p> <p>22 reactions that are specific to the TVT and</p> <p>23 TTVT-Exact?</p> <p>24 A. In my opinion, all you need to</p>

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<p>1 put in that -- if I was writing the 2 regulation, I think that what's specific 3 to TVT and midurethral slings is the risk 4 of, and synthetic slings, is the risk of 5 exposure and extrusion.</p> <p>6 Q. And that's all you would put in 7 the IFU based upon your understanding of 8 the federal regulations?</p> <p>9 A. No, I didn't say that and you 10 didn't ask me that. I said if I was 11 making the regulation.</p> <p>12 So, the regulation is of what 13 needs to be specific to that procedure and 14 unique -- no, specific and unique to the 15 device, not necessarily the procedure.</p> <p>16 Q. So in your opinion, what needs 17 to be in the IFU for TVT and TVT-Exact 18 regarding adverse events?</p> <p>19 MR. ROSENBLATT: Object to form. 20 I just want to make sure you're 21 not asking about contraindications?</p> <p>22 MR. BENTLEY: I said adverse 23 events, right.</p> <p>24 A. What's required by the CFR.</p>	<p>1 Q. Do you know the question? 2 MR. ROSENBLATT: Can we go back 3 and read that where he answered "mesh 4 erosion and extrusion"?</p> <p>5 MR. BENTLEY: I don't mean to 6 belabor this. I'm going to keep 7 going. I know he hasn't answered.</p> <p>8 BY MR. BENTLEY:</p> <p>9 Q. As you sit here today -- 10 MR. ROSENBLATT: Hold on. I 11 just want to hear what the previous 12 question and answer was, Greg. I'm 13 not trying to be rude and interrupt.</p> <p>14 If you want to spend more time 15 on it, I just want to make sure that 16 he already did.</p> <p>17 MR. BENTLEY: He's going to say 18 two things. We've already spent more 19 time talking about it than the actual 20 answer would be if you'd give the 21 answer.</p> <p>22 MR. ROSENBLATT: I think he did 23 give the answer. I just want to try 24 to figure it out here.</p>
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<p>1 Q. That's not my question. 2 In your opinion as a expert in 3 this case that's offering the opinion that 4 the TVT IFU is appropriate and adequately 5 warned, in your opinion, what adverse 6 events need to be in the TVT and 7 TVT-Exact?</p> <p>8 A. In my opinion, from what was 9 known at that point in time, the IFU was 10 adequate.</p> <p>11 Q. I didn't ask that. 12 In your opinion, as you sit here 13 today with the knowledge you've got, what 14 adverse events need to be listed in the 15 TVT IFU and the TVT-Exact IFU?</p> <p>16 MR. ROSENBLATT: Object to form; 17 asked and answered.</p> <p>18 He said mesh erosion and 19 exposure and that was it.</p> <p>20 MR. BENTLEY: He hasn't 21 answered -- you can look at the 22 transcript.</p> <p>23</p> <p>24 BY MR. BENTLEY:</p>	<p>1 (The requested portion of the 2 record was read by the Court Reporter.)</p> <p>3 MR. BENTLEY: He's talking about 4 writing the regulation. I didn't ask 5 about writing regulation.</p> <p>6 MR. ROSENBLATT: Fair enough. 7 MR. BENTLEY: Would you read 8 back my question, please? 9 (The requested portion of the 10 record was read by the Court Reporter.)</p> <p>11 A. So, in my opinion, the adverse 12 events that need to be there are -- 13 include damage to vessels, nerves, 14 bladder, urethra or bowel and the 15 possibility of extrusion, erosion, fistula 16 formation or inflammation.</p> <p>17 Q. Are all of those complications 18 unique to the TVT and TVT-Exact?</p> <p>19 A. No, they're not.</p> <p>20 Q. So what's your standard for what 21 needs to be in the IFU?</p> <p>22 A. My standard for what needs to be 23 in the IFU is based on the government 24 guidelines. Or, if I can correct,</p>

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<p>1 government regulations as opposed to 2 guidelines.</p> <p>3 Q. Do you hold yourself out as an 4 expert in biomedical engineering?</p> <p>5 A. I hold myself out as an expert 6 when it comes to polypropylene and 7 synthetic materials and their 8 biocompatibility when placed in the pelvic 9 floor.</p> <p>10 Q. Have you ever designed a mesh?</p> <p>11 A. I've discussed mesh properties 12 with industry, but -- I've discussed 13 different mesh properties with industry 14 and how to design some meshes that we may 15 be doing research on.</p> <p>16 Q. And are you doing research on 17 partially absorbable meshes?</p> <p>18 A. Yes. And there's going to be 19 some confidential information that I'm not 20 going to be able to share.</p> <p>21 Q. What's the purpose of 22 researching partially absorbable meshes?</p> <p>23 A. What's the purpose of 24 resourcing -- to see and try to find out</p>	<p>1 would be a benefit. But there's no proof 2 at this point in time, there's no clinical 3 data at this point in time that an 4 absorbable mesh would provide that 5 efficacy, nor is there any clinical data 6 that the absorbable mesh that we're 7 working on for slings would be a safer 8 option for them.</p> <p>9 Q. You're working on absorbable 10 mesh for the treatment of incontinence; is 11 that correct?</p> <p>12 A. No. We're working on properties 13 of absorbable mesh in rabbits, so, and 14 comparing that to polypropylene.</p> <p>15 Q. And are you testing inflammation 16 in the rabbit? Or what's your endpoint?</p> <p>17 A. There are multiple endpoints to 18 the --</p> <p>19 MR. ROSENBLATT: Object to form. 20 To the extent you can discuss it 21 and it's not confidential, you can 22 answer.</p> <p>23 A. There are multiple endpoints 24 to -- in the protocol. I can't go through</p>
<p style="text-align: center;">Page 223</p> <p>1 if there is a different option for 2 patients using a partially absorbable -- 3 an absorbable mesh as opposed to a 4 permanent mesh.</p> <p>5 Q. And what's the potential benefit 6 of a partially absorbable meshes?</p> <p>7 A. The potential benefit is that 8 this mesh gets absorbed and it does not 9 stay there forever.</p> <p>10 Q. And what's the ultimate clinical 11 outcome that that could potentially be for 12 a patient?</p> <p>13 MR. ROSENBLATT: Object to form. 14 I just want to make sure that 15 we're talking about incontinence.</p> <p>16 MR. BENTLEY: Yes.</p> <p>17 A. Talking about incontinence, so, 18 we know that there is a long-term risk of 19 placing in a polypropylene mesh. We know 20 that although on the short-term most of 21 the complications happen, you can get 22 long-term complications as well. And if 23 we can reduce that complication rate, mind 24 you with the same efficacy, then there</p>	<p style="text-align: center;">Page 225</p> <p>1 all those right now, nor do I remember 2 every single one of them.</p> <p>3 Q. As a physician and an expert in 4 this case, what endpoints would you look 5 for in researching a model involving 6 partially absorbable mesh versus permanent 7 mesh?</p> <p>8 A. So, some of the things that I 9 may look for will be inflammation, chronic 10 foreign body reaction that we discussed, 11 tissue strength, histopathology. This 12 is --</p> <p>13 Q. Do you consider yourself -- I'm 14 sorry, were you done?</p> <p>15 A. This is a very early study, 16 obviously.</p> <p>17 Q. Do you consider yourself an 18 expert in histopathology?</p> <p>19 A. I have reviewed -- when I have 20 reviewed slides on the pelvic floor, I've 21 reviewed slides with pathologists. I've 22 done this ever since I was a medical 23 student. I have -- I will be reviewing 24 the slides from these rabbits that will</p>

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<p>1 come out, and I've been reviewing that 2 throughout my career. 3 Q. You'll personally be reviewing 4 the slides, or you're going to send them 5 to a pathologist for their review? 6 A. Well, we're going to review them 7 with them. 8 So, I'm not a board certified 9 pathologist, but I've been looking at 10 slides throughout my entire career and 11 consider myself somewhat of an expert. 12 Q. Why don't you order -- why do 13 you only order a gross specimen review 14 when you send something to a pathologist 15 that's been explanted? 16 A. There's no other benefit to the 17 patient, and I would not want in order to 18 go any further. What benefit would she 19 get out of me after taking out the mesh, 20 as opposed to spending the insurance 21 company's money? 22 Q. What is the clinical 23 significance, in your opinion, of a mesh 24 roping?</p>	<p>1 makes the pores collapse, do you have an 2 opinion as to whether that causes 3 shrinkage and contraction? 4 MR. ROSENBLATT: Object to form. 5 Are you asking a hypothetical? 6 BY MR. BENTLEY: 7 Q. If you know. 8 A. Say that again. 9 Q. If the mesh ropes and curls, 10 thereby causing the pores to collapse, 11 does that cause shrinkage and contraction? 12 MR. ROSENBLATT: Object to form. 13 A. What I understand is that if the 14 pore size theoretically is less than a 15 certain size, you may get increased 16 scarring. 17 Q. And that can happen through 18 roping, correct? 19 A. I wouldn't say roping. It -- I 20 would say it can happen through pore 21 collapse. 22 If it ropes, it still doesn't 23 have to collapse the pore, right? 24 Q. If you want to look on page 22</p>
<p style="text-align: center;">Page 227</p> <p>1 MR. ROSENBLATT: Object to form. 2 A. The clinical significance if a 3 mesh ropes? 4 Q. Yes. 5 A. So, if it -- if that mesh ropes, 6 it can then get too tight and get too 7 tense and migrate into structures that we 8 don't want it to go in. It can create 9 increased scarring if it ropes. 10 Q. How does roping mesh cause 11 increased scarring? 12 A. So, if -- you may -- with a 13 roping mesh, you may get a band-like 14 effect in the vagina, and I would 15 attribute that to scarring. It's not 16 like -- I would attribute that to 17 scarring. 18 Q. Does the mesh roping and curling 19 affect the pore size? 20 A. It may, but I will tell you I 21 have not seen mesh roping and curling. I 22 know it's been reported. I've not seen 23 that with midurethral slings. 24 Q. If the mesh ropes and curls and</p>	<p style="text-align: center;">Page 229</p> <p>1 of your report, Doctor, you have a 2 paragraph that starts out "However." 3 A. Okay. 4 Q. You say: "Additionally, when 5 placing the sling and moving the plastic 6 sheathes, as directed in the IFU," you 7 state: "averts the mesh from roping and 8 curling, thereby keeping the pores open 9 which prevents shrinkage and contraction." 10 A. Yeah, and I think I already 11 stated that I do not see roping and 12 curling occurring with midurethral slings. 13 Q. Maybe I just don't understand. 14 Your opinion is that roping and 15 curling causes the pores to collapse, 16 correct? 17 A. I said roping and curling may 18 cause the pores to collapse. 19 Q. Okay. And if the pores 20 collapse, that can cause shrinkage and 21 contraction, correct? 22 A. I don't think the mesh shrinks. 23 I think that you can get increased 24 scarring if the pores collapse.</p>

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<p>1 Q. If the pores collapse, you can 2 get increased scarring, is that what you 3 testified to?</p> <p>4 A. If the pores collapse or if you 5 have small pores, there may be increased 6 scarring.</p> <p>7 Q. Okay. And increased scarring 8 leads to shrinkage and contraction, 9 correct?</p> <p>10 A. Increased scarring may lead to 11 shrinkage and contraction.</p> <p>12 Q. And I mean, you're stating here 13 in your report that's what the importance 14 of having open pores is; is that correct?</p> <p>15 A. I'm not going to -- you want to 16 put that mesh in that the pores stay open, 17 yes.</p> <p>18 Q. Do you have any studies that 19 provide measurements of what the pore size 20 is after it's been implanted?</p> <p>21 A. I don't have any particular 22 studies, but I can show you a picture of, 23 and we can show it later, of a picture of 24 a transvaginal mesh that is seen</p>	<p>1 Did I read that correctly?</p> <p>2 A. Yes, you did.</p> <p>3 Q. And you stand by that opinion, 4 right?</p> <p>5 A. Yes, I do. And it's also backed 6 by the nice study in the UK that I think 7 that came out from 2014.</p> <p>8 Q. And you state: "It's a suitable 9 and one of the most appropriate meshes."</p> <p>10 Right?</p> <p>11 My question is what other 12 suitable and appropriate meshes exist 13 right now?</p> <p>14 MR. ROSENBLATT: Object to form. 15 You're asking about --</p> <p>16 MR. BENTLEY: The sentence in 17 the report.</p> <p>18 MR. ROSENBLATT: But you're 19 asking about incontinence right now?</p> <p>20 MR. BENTLEY: I'm asking in this 21 sentence he says that the mesh is a 22 suitable and appropriate mesh for 23 implant for the treatment of SUI.</p> <p>24 BY MR. BENTLEY:</p>
<p>1 abdominally without any evidence of pore 2 collapse.</p> <p>3 THE WITNESS: Want to pull that 4 picture out?</p> <p>5 MR. ROSENBLATT: He's got it 6 over there.</p> <p>7 MR. BENTLEY: I want to stick 8 with slings right now because we're in 9 the sling report.</p> <p>10 A. So, I mean, we're not taking out 11 slings with patients who are doing well 12 with them, so you're not going to find 13 that.</p> <p>14 Q. If you could please turn to page 15 27.</p> <p>16 A. Okay.</p> <p>17 Q. You have a paragraph that starts 18 "As a result."</p> <p>19 Do you see that?</p> <p>20 A. Yes.</p> <p>21 Q. You say: "The TVT mesh is a 22 suitable and currently one of the most 23 appropriate mesh implants for the 24 treatment of SUI."</p>	<p>1 Q. My question is what other 2 products are suitable and appropriate for 3 the treatment of SUI?</p> <p>4 A. So, the most two suitable ones 5 that I'm aware of right now are the TVT 6 mesh as well as the Boston Scientific 7 Advantage mesh for slings.</p> <p>8 Q. Do you have any understanding or 9 appreciation of the difference in those 10 two meshes?</p> <p>11 A. They are very similar. We can 12 pull out the Moalli study that I think has 13 that in there. But they are very, very 14 similar in terms of I think the mesh fiber 15 thickness is exactly the same, and it 16 could be that the Boston Scientific pore 17 size is slightly less, but it's above 1 18 millimeter. And I think the Caldera 19 slings are appropriate as well, but they 20 don't have the same long-term data behind 21 them as the two others do.</p> <p>22 Q. And those are three different 23 mesh constructions, correct?</p> <p>24 A. Well, the Boston Scientific</p>

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<p>1 Advantage and the TVT are extremely 2 similar. 3 Why don't we pull out the study 4 and take a look? 5 Q. I'm just trying to understand 6 your sentence here. 7 A. So, I'm saying -- 8 Q. Obviously the mesh knitting is a 9 different design for different 10 manufacturers; isn't that correct? It's 11 proprietary design? 12 A. Correct. Correct. 13 Q. And that's going to necessarily 14 make different pore size, albeit you're 15 saying fairly similar, correct? 16 A. Mm-hm. 17 Q. And that's going to create 18 different mesh weight, correct? 19 A. It may create different mesh 20 weight, yeah, the total weight. 21 Q. And the mesh geometry or 22 knitting design will create a different 23 flexibility property, correct? 24 A. It can, correct. And if I</p>	<p>1 MR. BENTLEY: I mean, I don't 2 have a question pending. 3 MR. ROSENBLATT: Sure. 4 BY MR. BENTLEY: 5 Q. Doctor, what's your definition 6 of "state of the art"? 7 A. I don't know if I have a total 8 strict definition of "state of the art." 9 I think state of the art is what is 10 considered the best procedure that we have 11 available at the time. 12 Q. What's your basis then for 13 saying the design of the TVT is state of 14 the art? 15 A. I think that right now, the 16 design of the TVT was a revolutionary 17 concept and it is one of the standards 18 that other slings should be compared 19 against or the data on that type of sling 20 should be compared against if you're going 21 to change. 22 Q. So, the mesh in the TVT, is that 23 mesh specifically, the design of that 24 mesh, is that the state of the art of the</p>
<p>1 recall, the Boston Scientific mesh and the 2 Advantage mesh, they're both a hundred 3 grams per meters -- per centimeter 4 squared. They're both a fiber of .15 5 millimeters, and the main difference is 6 their pore size. 7 Another difference in the 8 midurethral portion is it's heat-sealed 9 and it hangs on the other side. 10 Q. And they're going to have 11 different tensile strength based on their 12 knitting, correct? 13 A. Yes. 14 And if we can look at the Moalli 15 study, it probably has tensile strength in 16 there. I don't remember that. 17 MR. ROSENBLATT: You have it in 18 your report. 19 THE WITNESS: Yeah, but is 20 tensile strength in there? I'm not 21 looking. 22 MR. ROSENBLATT: You have it on 23 page 26. 24 THE WITNESS: Okay.</p>	<p>1 mesh? 2 A. I think the whole procedure was 3 a state of the art procedure. It was a, 4 you know, totally different concept and it 5 changed the way we treat stress urinary 6 incontinence in this country. 7 Q. So, I think I understand, the 8 design of the TVT procedure itself, in 9 your opinion, that's state of the art? 10 A. It was state -- yes, it's state 11 of the art. 12 Q. And in that procedure, you use a 13 mesh, and you've just discussed several 14 different mesh products that are sold by 15 different companies that you think are all 16 suitable and appropriate for mesh 17 implantation; is that fair? 18 A. Yes, there are different 19 companies that have suitable meshes. 20 Q. And those meshes have slight 21 differences, as we have discussed, based 22 on their knitting and various design 23 properties, correct? 24 A. Correct.</p>

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<p>1 Q. Doctor, there's been a -- we've 2 discussed this somewhat, but there's been 3 a various selection of different materials 4 that have been used as implants to treat 5 incontinence through the history of 6 treatment for incontinence; is that 7 correct?</p> <p>8 A. Correct.</p> <p>9 Q. And some of those materials were 10 Gore-Tex or Mersilene or polyester, 11 correct?</p> <p>12 A. Correct, yes.</p> <p>13 Q. And each one of the different 14 products had different results; isn't that 15 correct?</p> <p>16 A. Correct.</p> <p>17 Q. And a lot of the variation is 18 driven by, one, the material that goes 19 into making the product; is that correct?</p> <p>20 A. One of the components is the 21 material, yes.</p> <p>22 Q. And some other variation could 23 be by the way that material is made into 24 the mesh implant, the way it's designed;</p>	<p>1 Q. And those different properties 2 and additives and designs actually have 3 implications at the ultimate level for the 4 patient; is that correct?</p> <p>5 MR. ROSENBLATT: Object to form.</p> <p>6 A. They may. I don't know if we're 7 going to be able to drill down and be 8 specific as to which product has, or which 9 additive, quote/unquote, has the specific 10 complication.</p> <p>11 Q. That's why it would be important 12 to look at safety and efficacy information 13 specific to the specific product; isn't 14 that correct?</p> <p>15 MR. ROSENBLATT: Object to form.</p> <p>16 BY MR. BENTLEY:</p> <p>17 Q. You wouldn't want to establish 18 the safety of one product based off of 19 some other polypropylene product that has 20 a different design, would you?</p> <p>21 A. Well, I think there are some 22 assumptions that you can make and, at that 23 point in time, of how similar or 24 dissimilar the meshes are. If you're</p>
<p>1 is that correct?</p> <p>2 A. The way it's knitted or weaved 3 is what you're getting at.</p> <p>4 Q. Sure.</p> <p>5 A. Okay.</p> <p>6 Q. And that will affect various 7 properties, such as weight, density, 8 flexibility, tensile strength, correct?</p> <p>9 A. Well, I think the density of the 10 fiber stays the same depending on what 11 fiber you use, but the weight of the mesh, 12 sure.</p> <p>13 Q. The ultimate mesh will have 14 different characteristics based on the 15 design of the mesh, correct?</p> <p>16 A. Correct.</p> <p>17 Q. So, there is some variation in 18 different mesh products even though they 19 all started at polypropylene; is that 20 correct?</p> <p>21 A. That's correct. There are 22 different additives that I'm aware of that 23 companies put in in their polypropylene 24 that are proprietary.</p>	<p>1 going to show me a mesh and that's a .2 2 millimeter pore size and say use this for 3 stress urinary incontinence, I wouldn't 4 use that.</p> <p>5 Q. But if you had two products, 6 both made of polypropylene, similar width, 7 thickness, with different pore geometry, 8 you'd want to look at the safety 9 information for the specific one you're 10 using; is that fair?</p> <p>11 A. It's one of the components that 12 I would look at. It's not the only 13 component about the product or device that 14 I would look at and take into 15 consideration.</p> <p>16 Q. Was it important to you that 17 Ulmsten found no defect in healing in his 18 initial study?</p> <p>19 A. Can you tell me what you're 20 referring to?</p> <p>21 Q. I'm sorry. 22 You know who Professor Ulmsten 23 is, don't you?</p> <p>24 A. Yes.</p>

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<p>1 Q. Who is Professor Ulmsten?</p> <p>2 A. He was one of the,</p> <p>3 quote/unquote, fathers of the TTVT</p> <p>4 procedure.</p> <p>5 Q. And you cite to him in your</p> <p>6 report as Ulmsten developed the TVT,</p> <p>7 correct?</p> <p>8 A. Yes.</p> <p>9 Q. And Ulmsten did the first study</p> <p>10 on TTVT using Ethicon's Prolene mesh; is</p> <p>11 that correct?</p> <p>12 A. Yeah.</p> <p>13 Can you tell me what page you're</p> <p>14 on there?</p> <p>15 Q. On page 27 of your report, at</p> <p>16 the bottom you begin discussing the</p> <p>17 Ulmsten prototype.</p> <p>18 Do you see that?</p> <p>19 A. Yes, I do.</p> <p>20 Q. And then the next sentence</p> <p>21 you're discussing the Falconer/Ulmsten '96</p> <p>22 studies.</p> <p>23 Do you see that?</p> <p>24 A. Yes, I do.</p>	<p>1 testimony for the jury that you're</p> <p>2 unconcerned that Ulmsten --</p> <p>3 MR. BENTLEY: Strike that.</p> <p>4 Q. If evidence shows that Ulmsten,</p> <p>5 the creator of this device and the initial</p> <p>6 publication regarding this, if he</p> <p>7 misrepresented that there was no defect in</p> <p>8 healing, you're not concerned about that?</p> <p>9 MR. ROSENBLATT: Object to form;</p> <p>10 mischaracterization; lack of</p> <p>11 foundation.</p> <p>12 A. So, can you repeat the question?</p> <p>13 Q. Sure.</p> <p>14 At trial, do you intend to tell</p> <p>15 the jury that you're not concerned that</p> <p>16 Ulmsten may have misrepresented --</p> <p>17 MR. BENTLEY: Strike that.</p> <p>18 Q. If you're presented with</p> <p>19 evidence at trial, do you intend to tell</p> <p>20 the jury that you're not concerned if</p> <p>21 Ulmsten misrepresented the fact that TTVT</p> <p>22 in the initial study did indeed have a</p> <p>23 healing defect? Does that not concern</p> <p>24 you?</p>
<p>1 Q. And then on the next page, a</p> <p>2 subsequent study for a publication you</p> <p>3 say: Ulmsten '96 discussed the</p> <p>4 improvements in finding no defect in</p> <p>5 healing."</p> <p>6 Do you see that?</p> <p>7 A. Yes, I do. In 1996 he did write</p> <p>8 that.</p> <p>9 Q. And that's the first study where</p> <p>10 he's using Prolene for TTVT; is that</p> <p>11 correct?</p> <p>12 A. That I'm aware of, that's</p> <p>13 correct.</p> <p>14 Q. And you state that he found no</p> <p>15 defect in healing, correct?</p> <p>16 A. Correct.</p> <p>17 Q. Would it concern you if he</p> <p>18 misrepresented that result?</p> <p>19 A. At this point in time, it</p> <p>20 doesn't concern me because the proven</p> <p>21 safety and efficacy and multiple Level I</p> <p>22 studies have shown that the device is safe</p> <p>23 and efficacious.</p> <p>24 Q. So just so I'm clear, your</p>	<p>1 Page 243</p> <p>1 MR. ROSENBLATT: Same objection.</p> <p>2 A. I would be concerned about</p> <p>3 anybody who publishes a research article</p> <p>4 if they misrepresent what they found.</p> <p>5 I'm going to assume that he</p> <p>6 didn't misrepresent it.</p> <p>7 Q. Okay.</p> <p>8 A. But if you tell me now that</p> <p>9 there was an exposure rate of 2 percent,</p> <p>10 I'll -- I believe it and I'm not going to</p> <p>11 base the credibility of Ulmsten on what</p> <p>12 the information that we have today.</p> <p>13 Q. Would it concern you if</p> <p>14 information showed that there was a defect</p> <p>15 in healing and that Ulmsten had a</p> <p>16 pay-for-play agreement regarding the</p> <p>17 product?</p> <p>18 MR. ROSENBLATT: Objection;</p> <p>19 lack of foundation and</p> <p>20 mischaracterization.</p> <p>21 BY MR. BENTLEY:</p> <p>22 Q. You can answer.</p> <p>23 A. I understand that Ulmsten was</p> <p>24 paid --</p>

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<p>1 MR. ROSENBLATT: Argumentative.</p> <p>2 A. I understand that Ulmsten was</p> <p>3 paid for his -- the product, and I</p> <p>4 understand that he did get money for it.</p> <p>5 What I do think is if someone</p> <p>6 has product information or comes up with a</p> <p>7 device, they should be able to be</p> <p>8 compensated with an industry if it's their</p> <p>9 intellectual property that's going to be</p> <p>10 used.</p> <p>11 Q. My question was just do you</p> <p>12 intend to tell the jury that that doesn't</p> <p>13 concern you if he misrepresented data that</p> <p>14 he was getting paid to present it</p> <p>15 favorably?</p> <p>16 MR. ROSENBLATT: Object to form.</p> <p>17 Greg, let's pull it out and look</p> <p>18 at it if you want to ask him about it.</p> <p>19 MR. BENTLEY: I'm just talking</p> <p>20 about the hypothetical.</p> <p>21 We know what the data shows.</p> <p>22 MR. ROSENBLATT: Well, let's</p> <p>23 pull it out and look at the data so he</p> <p>24 can give you a better answer.</p>	<p>1 layman?</p> <p>2 Q. To me maybe.</p> <p>3 A. Yeah, no problem.</p> <p>4 So, most commonly what I say to</p> <p>5 people who ask me what I do is I do</p> <p>6 urogynecological, that's female pelvic</p> <p>7 reconstructive medicine. The most common</p> <p>8 things that we deal with would be pelvic</p> <p>9 organ prolapse, which is when something is</p> <p>10 falling down or out of the vagina, and the</p> <p>11 second most common thing that we will</p> <p>12 manage and treat is stress urinary</p> <p>13 incontinence -- is urinary incontinence,</p> <p>14 and then they may ask me what urinary</p> <p>15 incontinence is, and I may explain to them</p> <p>16 the difference between stress and urge</p> <p>17 incontinence.</p> <p>18 Q. So you would classify yourself</p> <p>19 as a urogynecologist, right?</p> <p>20 A. I would classify myself as a</p> <p>21 female pelvic medicine reconstructive</p> <p>22 surgeon because that's what the board</p> <p>23 certification is, but it's easier to say</p> <p>24 urogynecologist, for sure.</p>
<p>1 MR. BENTLEY: I don't care about</p> <p>2 that.</p> <p>3 BY MR. BENTLEY:</p> <p>4 Q. The hypothetical, just go with</p> <p>5 this assumption. Assuming the data showed</p> <p>6 that Ulmsten had healing defect in his</p> <p>7 initial study and he was getting paid</p> <p>8 based on whether or not he had no defects,</p> <p>9 if he misrepresented that data, would that</p> <p>10 concern you? My question is only would</p> <p>11 that concern you?</p> <p>12 MR. ROSENBLATT: Object to form;</p> <p>13 lack of foundation.</p> <p>14 A. It may concern me on his</p> <p>15 character, but it's not going to change</p> <p>16 the way I feel and my opinions on</p> <p>17 midurethral slings today.</p> <p>18 Q. Doctor, what would you consider,</p> <p>19 or how would you describe your medical</p> <p>20 expertise or specialty?</p> <p>21 A. I don't understand. What do you</p> <p>22 mean?</p> <p>23 Q. How do you describe what you do?</p> <p>24 A. To people, let's say to a</p>	<p>1 Q. And that's of course different</p> <p>2 than just a gynecologist, correct?</p> <p>3 A. That's correct.</p> <p>4 Q. And is that different from, in</p> <p>5 your interpretation, is that different</p> <p>6 from a urologist?</p> <p>7 A. From a general urologist, yes.</p> <p>8 Q. And each of those specialties</p> <p>9 have, I presume, different certifications?</p> <p>10 A. Yes. So, both urology and</p> <p>11 obstetrics and gynecology have general</p> <p>12 board certification, and they also have</p> <p>13 subspecialty board certification.</p> <p>14 Q. And they have different</p> <p>15 training, I presume; is that correct?</p> <p>16 A. Well, the training for the</p> <p>17 subspecialty for female pelvic medicine is</p> <p>18 supposed to be, at this point in time, a</p> <p>19 little more, what's the word I'm looking</p> <p>20 for, structured, for lack of better terms</p> <p>21 right now. Standardized, structured.</p> <p>22 Q. Fine.</p> <p>23 Is there different</p> <p>24 accreditation, I would presume, for the</p>

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<p>1 different subspecialties?</p> <p>2 A. So, there's a combined board for</p> <p>3 the female pelvic medicine and</p> <p>4 reconstructive surgery certification, and</p> <p>5 I'm not exactly sure on how the</p> <p>6 credentialing works on the urology side.</p> <p>7 They get their female pelvic medicine and</p> <p>8 reconstructive surgery from the urology</p> <p>9 side, but it's sort of a combined board</p> <p>10 between OB-GYN and urology. There are</p> <p>11 three people from each specialty on that</p> <p>12 board.</p> <p>13 Q. And there's urology-focused</p> <p>14 journals, correct?</p> <p>15 A. Yes, there are.</p> <p>16 Q. And there's gynecology-focused</p> <p>17 journals, correct?</p> <p>18 A. Yes, there are.</p> <p>19 Q. And there's actually, I think,</p> <p>20 reconstructive pelvic medicine-focused</p> <p>21 journals, correct?</p> <p>22 A. Yes.</p> <p>23 Q. And each of those journals</p> <p>24 brings a different perspective to the</p>	<p>1 A. Yeah, and I think I actually</p> <p>2 wrote about that in my report. In the</p> <p>3 late '90s, urologists were more commonly</p> <p>4 doing pubovaginal slings for urinary</p> <p>5 incontinence and that's where their</p> <p>6 training came from. And they were almost</p> <p>7 suggesting, and some urologists were</p> <p>8 suggesting that everyone if they were</p> <p>9 getting an anti-incontinence procedure, a</p> <p>10 pubovaginal sling should be the primary</p> <p>11 procedure that you're performing.</p> <p>12 Gynecologists, as a general</p> <p>13 rule, were more commonly performing Burch</p> <p>14 procedures.</p> <p>15 Q. You were doing Burch procedures</p> <p>16 in that time period predominantly?</p> <p>17 A. So, that was one of the things</p> <p>18 that I got lucky with, I think, in terms</p> <p>19 of my training. That yes, we did</p> <p>20 abdominal procedures, but we also did</p> <p>21 pubovaginal sling procedures. We also did</p> <p>22 bone anchored procedures, not that bone</p> <p>23 anchors are the way to go today, but I did</p> <p>24 have -- and we did urethrolysis. So I</p>
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<p>1 table; is that fair?</p> <p>2 A. Yes, they do.</p> <p>3 Q. It's a little different</p> <p>4 knowledge and practice in each one of</p> <p>5 those?</p> <p>6 A. Theoretically. I mean, yes,</p> <p>7 theoretically there may be different ways</p> <p>8 of looking at things, although in the</p> <p>9 female pelvic medicine side, there has</p> <p>10 been a lot of work in the last ten years</p> <p>11 to try to more standardize that, whether</p> <p>12 it's coming from the urology side or</p> <p>13 whether it's coming from the GYN side.</p> <p>14 Q. In the last ten years, the</p> <p>15 urology and gynecology have kind of</p> <p>16 converged into female pelvic medicine</p> <p>17 reconstructive surgery?</p> <p>18 A. Right.</p> <p>19 Q. And prior to them converging in</p> <p>20 the middle, urologists might have</p> <p>21 preferred one procedure for the same</p> <p>22 indication as compared to gynecologists</p> <p>23 were doing a different procedure for that</p> <p>24 same indication?</p>	<p>1 felt I got extensive training on both</p> <p>2 sides of the spectrum, and I felt that I</p> <p>3 was lucky because of that.</p> <p>4 Q. You don't have any criticism of</p> <p>5 the urologists for preferring the</p> <p>6 pubovaginal sling, do you?</p> <p>7 A. No, and I understand where that</p> <p>8 came from.</p> <p>9 Q. It was based upon their</p> <p>10 knowledge and training and they thought</p> <p>11 that was the better procedure?</p> <p>12 A. Yeah, they're entitled.</p> <p>13 Q. And the other side, you don't</p> <p>14 have any criticism of the gynecologists</p> <p>15 who thought, based on their training and</p> <p>16 knowledge, the Burch was better?</p> <p>17 MR. ROSENBLATT: Object to form.</p> <p>18 Are you talking about then or</p> <p>19 now?</p> <p>20 MR. BENTLEY: Then.</p> <p>21 MR. ROSENBLATT: Okay.</p> <p>22 BY MR. BENTLEY:</p> <p>23 Q. You discussed in your report</p> <p>24 that in the late '90s when urology and</p>

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<p>1 gynecology were separate before they 2 converged that there was different 3 preferences in how to treat incontinence, 4 that the urologists preferred to do the 5 pubovaginal sling, correct?</p> <p>6 A. Correct.</p> <p>7 Q. And back then, the 8 gynecologists --</p> <p>9 A. I would say most urologists, not 10 all.</p> <p>11 Q. Of course.</p> <p>12 And conversely, gynecologists 13 preferred to do the open Burch procedure, 14 correct?</p> <p>15 A. Correct.</p> <p>16 Q. And you don't have any criticism 17 of the gynecologists' preference for doing 18 the Burch back then, correct?</p> <p>19 A. No. I think it was the 20 procedure that you can do back then.</p> <p>21 Q. And that's because they had 22 training and knowledge that indicates to 23 them that this was the more appropriate 24 procedure for them to recommend in the</p>	<p>1 Burch procedure for a primary repair as 2 opposed to an autologous sling procedure.</p> <p>3 Q. Doctor, in your report, you 4 mention that every patient is slightly 5 different, and that goes without saying, 6 right?</p> <p>7 A. Correct.</p> <p>8 Q. And every surgeon is different 9 how they would like to do something, 10 correct?</p> <p>11 A. Slightly, yes.</p> <p>12 Q. And a surgeon's differing 13 preference on how to do it is based in 14 part on his or her experience, correct?</p> <p>15 A. Correct, and it may be based on 16 their height, their weight.</p> <p>17 I don't know what to tell you.</p> <p>18 Q. And based upon their knowledge 19 based on what journals they're reading?</p> <p>20 A. Correct.</p> <p>21 Q. And what training programs 22 they're going to, or CMEs, correct?</p> <p>23 A. Correct.</p> <p>24 Q. And everyone's slightly</p>
<p>1 majority of the cases, and you're not 2 critical of that, are you?</p> <p>3 A. I'm not going to criticize what 4 they picked. I think that most people 5 back then did the procedure that they were 6 comfortable and trained with. If they 7 didn't know how to do a pubovaginal sling, 8 I don't think they were going to offer it.</p> <p>9 Q. Because they had a different 10 understanding and a different knowledge 11 base and that led them to a different 12 preference back then; isn't that correct?</p> <p>13 A. Yes, that led them to, based on 14 their training and education, led them to 15 the preference of one over the other.</p> <p>16 Q. Which may have been different 17 for urologists versus gynecologists, 18 correct?</p> <p>19 A. Yeah, I don't recall -- I'm 20 not -- I don't recall what the specific 21 training for urologists were back then. I 22 can tell you what urogynecologists and 23 gynecologists were doing, but as a general 24 rule, we tended to lean more towards a</p>	<p>1 differently positioned, correct?</p> <p>2 A. You're talking about patients or 3 surgeon?</p> <p>4 Q. Well, actually both; isn't that 5 correct?</p> <p>6 A. Yeah, one surgeon may prefer to 7 position with one type of stirrups and 8 another surgeon may prefer to position 9 with another set of stirrups. One surgeon 10 may want more flexion of the hips, one 11 person may want less flexion of the 12 hips.</p> <p>13 Q. Doctor, you're a member of the 14 ACOG and AUGS, correct?</p> <p>15 A. Correct.</p> <p>16 Q. And ACOG and AUGS put out 17 practice bulletins, correct?</p> <p>18 A. Yes, they do.</p> <p>19 Q. And you rely upon those, right?</p> <p>20 A. It's one of the things I rely 21 on.</p> <p>22 Q. You cite to them in your 23 reliance materials, right?</p> <p>24 A. That's correct.</p>

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<p>1 Q. Would you consider them 2 important evidence?</p> <p>3 A. I think those are some things 4 you should take into consideration when 5 you're doing these procedures, yes.</p> <p>6 Q. What level of evidence would you 7 classify those position statements as?</p> <p>8 A. I would classify those position 9 statements as guidelines as opposed to a, 10 quote/unquote, level of evidence.</p> <p>11 Q. Got you.</p> <p>12 Do you have an opinion as to 13 whether TVT has rough edges or smooth 14 edges?</p> <p>15 MR. ROSENBLATT: Object to form.</p> <p>16 A. I don't have an opinion if one 17 is rough or smooth in particular.</p> <p>18 Q. If you want to look on page --</p> <p>19 A. I have an opinion that the 20 laser-cut TVT has a more of a rounded type 21 of edge and the TVT mechanical may have a, 22 quote/unquote, slightly pointier edge, and 23 how that feels to an individual surgeon 24 may be different.</p>	<p>1 product of the cutting process.</p> <p>2 Q. And that's part of the design of 3 the mesh, whether or not you design to be 4 laser-cut or machine-cut, right?</p> <p>5 A. I don't think it's the way of 6 the design of the mesh. I think it's the 7 way that you're cutting the mesh.</p> <p>8 Q. Which is part of the design of 9 the manufacturer, correct?</p> <p>10 A. Okay.</p> <p>11 Q. I mean, if the design 12 specifications call for laser-cut, that's 13 part of the design?</p> <p>14 A. Correct.</p> <p>15 Q. And conversely, if the design 16 calls for a machine-cut, that's part of 17 the design, right?</p> <p>18 A. Correct.</p> <p>19 Q. And the resulting rough or not 20 as smooth edges is inherently part of the 21 design, right?</p> <p>22 A. The edges are inherently part of 23 the design, yes.</p> <p>24 Q. Okay. On page 28 of your</p>
<p>1 Clinically, I don't think that 2 it makes a difference if you have -- that 3 I've seen in my patients or that I've been 4 reported if there's a difference between 5 those two particular type of edges.</p> <p>6 Q. So, laser-cut mesh is going to 7 have more of a smooth sealed edge; is that 8 correct?</p> <p>9 A. So, if you're touching one of 10 the edges.</p> <p>11 Q. Right.</p> <p>12 A. It's, yeah, it's smoother.</p> <p>13 Q. And machine-cut's going to have 14 a little bit rougher edge without the 15 sealed laser-cut process?</p> <p>16 A. I mean, I don't know if I 17 describe it as a rougher edge all the 18 time, but I think that it may have a 19 different type of a feel to it, yeah.</p> <p>20 Q. And the feel or roughness of the 21 edge, that's a product of the cutting 22 process; isn't that correct?</p> <p>23 A. Yeah, the edges are a product of 24 the cutting. How the edges turn out are a</p>	<p>1 report, you have a paragraph that starts 2 "A standard weight mesh."</p> <p>3 Do you see that?</p> <p>4 A. Yes.</p> <p>5 Q. And the second sentence you're 6 discussing the Prien-Larsen 2016 study and 7 you state that: "They recently published 8 a prospective study comparing 100 grams 9 per meter squared with low stiffness and 10 rough edges similar to TVT."</p> <p>11 Do you see that?</p> <p>12 A. Correct. That's how they 13 described it in the paper.</p> <p>14 Q. Well, you're saying that that's 15 similar to TVT, and there you're talking 16 about machine-cut; is that correct?</p> <p>17 A. Yeah.</p> <p>18 Can you pull out the paper, do 19 you mind?</p> <p>20 Q. I'm just talking about your 21 report. There's not a direct quote in 22 that sentence, is there?</p> <p>23 A. No, there is not.</p> <p>24 Q. So you're just saying that the</p>

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<p>1 rough edges are like the machine-cut TVT, 2 right?</p> <p>3 A. I said they're similar to the 4 TVT.</p> <p>5 Q. As we discussed, that would be 6 the machine-cut TVT as opposed to the 7 laser-cut?</p> <p>8 A. That's correct.</p> <p>9 Q. Doctor, you make a couple of 10 statements in your report talking about 11 your opinion as to what is commonly. 12 You're aware of that, right?</p> <p>13 A. That I used the word "commonly"?</p> <p>14 Q. Yes.</p> <p>15 A. I used it in my report. I don't 16 know how many times I used it, but it's in 17 there.</p> <p>18 Q. On page 23 of your report, you 19 have a paragraph that starts with "The TVT 20 procedure has been shown."</p> <p>21 Do you see that at the top?</p> <p>22 A. Yes.</p> <p>23 Q. And, I apologize, the paragraph 24 starts on page 22 and ends on 23.</p>	<p>1 that's published, as well as my 2 experience.</p> <p>3 Q. That's based upon the literature 4 that you've reviewed and your experience, 5 correct?</p> <p>6 A. Correct.</p> <p>7 Q. Because you really -- we have no 8 way of knowing what every surgeon in the 9 U.S. and every geographic region and every 10 specialty reviews, right?</p> <p>11 MR. ROSENBLATT: Object to form.</p> <p>12 A. All I know is what every surgeon 13 and what every resident, and forget about 14 every resident and medical student should 15 be trained on. That's what I know.</p> <p>16 Q. Right.</p> <p>17 A. Would I know what everyone else 18 is thinking? Absolutely not.</p> <p>19 Q. And those can be, unfortunately, 20 slightly different; is that fair?</p> <p>21 A. I will agree with you.</p> <p>22 Q. Some surgeons may not be acutely 23 aware of all of the complications and 24 their frequency?</p>
<p>1 A. Okay.</p> <p>2 Q. In that sentence that carries 3 over from 22 to 23 you state: "Despite 4 the high success rate of TVT, there are 5 failures as with any procedure, and 6 surgeons are acutely aware that certain 7 types of patients may have higher success 8 rates than others."</p> <p>9 My question is is there a 10 difference in your report when you use a 11 phrase such as "acutely aware" versus 12 "commonly aware" or "commonly known"? How 13 are you choosing those?</p> <p>14 A. I probably didn't want to use 15 "commonly" so many times. That's what I 16 learned in writing class as, well, you're 17 not supposed to use the same word twice in 18 a paragraph. So that's probably why I 19 picked that word "acutely."</p> <p>20 Q. And when you're opining as to 21 what surgeons are acutely aware of, that's 22 based on your experience generally; is 23 that fair?</p> <p>24 A. That's based on the literature</p>	<p>1 A. So, in my opinion, if you're 2 doing a procedure, you should be aware of 3 the complications.</p> <p>4 Q. I give you that. They should 5 be.</p> <p>6 A. Okay.</p> <p>7 Q. But you would give me that they 8 may not actually be aware, unfortunately?</p> <p>9 A. Once again, I can't opine on 10 what people know or don't know. I can 11 only opine on what we're supposed to be 12 taught.</p> <p>13 Q. Appreciate that.</p> <p>14 And then on page 35, you have a 15 paragraph in the middle that begins with 16 "The surgical risks."</p> <p>17 A. Yes.</p> <p>18 Q. And you state: "The surgical 19 risks and complications for stress 20 incontinence procedures are commonly known 21 and not unique to TVT."</p> <p>22 Is that correct?</p> <p>23 A. That is correct, that's what's 24 written.</p>

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<p>1 Q. I think I understand now, your 2 opinion there is based upon what you think 3 they should know; is that correct?</p> <p>4 A. My opinion is based on what we 5 are required to teach and what I teach and 6 what I know my fellow urogynecologists 7 teach upon discussion with them.</p> <p>8 Q. Right. And that being said, we 9 still don't know exactly what every 10 surgeon knows, unfortunately?</p> <p>11 MR. ROSENBLATT: Object to form; 12 asked and answered.</p> <p>13 A. I can't opine on what people 14 know and what they don't know.</p> <p>15 Q. And there's no studies --</p> <p>16 A. There's no right answer for this 17 question.</p> <p>18 Q. There's no studies polling the 19 knowledge of surgeons as to their 20 knowledge of complications associated with 21 TVT products to treat incontinence, right?</p> <p>22 A. Say that again.</p> <p>23 Q. That was a great question, I'm 24 just going to read it back to you.</p>	<p>1 given was in 2013.</p> <p>2 Q. And of course the slings have 3 been implanted since at least 1998, right?</p> <p>4 A. Yes.</p> <p>5 Q. And on page 41, you have one 6 paragraph that begins "The possibility." 7 Are you with me?</p> <p>8 A. Yes.</p> <p>9 Q. And you say: "The possibility 10 of developing chronic pain and dyspareunia 11 are inherent to vaginal surgery 12 independently and do not need to be 13 explicitly mentioned in an IFU as every 14 implanting surgeon would have possessed 15 this knowledge through their education, 16 training and practice."</p> <p>17 And to maybe make this more 18 clear, should that state that implanting 19 surgeons should have possessed this 20 knowledge, in your experience, because we 21 have no basis of knowing what they knew, 22 right?</p> <p>23 MR. ROSENBLATT: Object to form.</p> <p>24 A. So, my understanding on the</p>
Page 267	Page 269
<p>1 There's no studies polling the 2 knowledge of all surgeons as to their 3 knowledge of complications associated with 4 the TVT products to treat incontinence, 5 right?</p> <p>6 A. I don't think there are any 7 studies. I'm not aware of any studies 8 that will attest to what doctor knows 9 about incontinence and what they don't 10 know about incontinence.</p> <p>11 I will tell you that there's a 12 certifying exam that if they want to be a 13 female pelvic medicine doctor will give 14 them certification in their knowledge of 15 the pelvic floor, for instance.</p> <p>16 And there's a certifying exam 17 for the specialty as well in OB-GYN which 18 they have to pass if they want to call 19 themselves a board certified physician.</p> <p>20 Q. When did the FPMS --</p> <p>21 A. FPMRS.</p> <p>22 Q. FPMRS exam, when did that 23 accreditation come out?</p> <p>24 A. The first time that exam was</p>	<p>1 educational process, and we have it -- I'm 2 going to say specific to OB-GYN, we can 3 talk about urology if you'd like, but 4 specific to OB-GYN, every single physician 5 when they do vaginal surgery is taught 6 that chronic pelvic pain and dyspareunia 7 can happen. It can happen after a vaginal 8 delivery and an episiotomy repair. It can 9 happen after hysterectomy. These are 10 complications that should have been known 11 by everyone. I can't imagine -- no one's 12 going through an OB-GYN residency without 13 doing a hysterectomy and no one's going 14 through an OB-GYN residency without doing 15 an episiotomy.</p> <p>16 Q. You're talking about just the 17 possibility of these complications 18 occurring, right?</p> <p>19 A. Correct.</p> <p>20 Q. And let's talk about the 21 frequency of these complications 22 happening, okay. We're limiting it to 23 frequency, not possibility.</p> <p>24 Are you with me?</p>

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<p>1 A. Yes.</p> <p>2 Q. Would you agree with me that not 3 everybody knows, necessarily, the true, 4 accurate frequency with which these 5 complications occur after the TVT 6 implantation?</p> <p>7 A. I can go based on the published 8 literature of what the frequency and the 9 complications are.</p> <p>10 Q. Right.</p> <p>11 A. Do we have a registry of every 12 single person who got a TVT in the world? 13 No, we don't.</p> <p>14 Q. All right. So, based off your 15 review of the literature, what's your 16 opinion as to the true rate of erosion 17 after TVT implantation?</p> <p>18 A. On my review of the literature, 19 it's approximately 2 percent.</p> <p>20 Q. And you've reviewed an extensive 21 amount of literature, right?</p> <p>22 A. Yes, I have.</p> <p>23 Q. And you understand that some 24 doctors haven't reviewed as much</p>	<p>1 Q. And not every physician has time 2 to do that, unfortunately, right?</p> <p>3 A. That is correct.</p> <p>4 Q. And so it's possible that 5 there's doctors out there that don't have 6 the same high level of knowledge of the 7 literature regarding TVT complications as 8 you do, right?</p> <p>9 A. I think they would have the 10 basic knowledge on the complications of a 11 TVT.</p> <p>12 Q. But they don't have your 13 explicit extensive knowledge regarding the 14 frequency that's in the literature?</p> <p>15 A. I don't -- they may not have 16 done the same amount of literature 17 searches, but I can't comment if they know 18 the frequency or not. That's pretty much 19 out there at 2 percent.</p> <p>20 Q. You just don't know what they 21 know, right?</p> <p>22 MR. ROSENBLATT: Object to form.</p> <p>23 A. Once again, I can't opine on 24 what they know. I can opine on what they</p>
<p style="text-align: center;">Page 271</p> <p>1 literature as you have. Would you agree 2 with that?</p> <p>3 A. I would agree that not every 4 doctor is reviewing as much literature in 5 this that I have, but the exposure rate is 6 something that is -- it's the most common 7 complication, almost, that we see when 8 we're talking about real complications as 9 opposed to like a urinary tract infection, 10 that anyone implanting that, anyone 11 implanting a foreign body would know that 12 exposure is a possibility.</p> <p>13 Q. And I'm not trying to talk about 14 possibility. I'll give you that.</p> <p>15 A. Okay.</p> <p>16 Q. I'm saying that you know there's 17 physicians out there that haven't had the 18 opportunity to review this amount of 19 extensive literature that you have.</p> <p>20 You agree with that, right?</p> <p>21 A. I agree with that, yes.</p> <p>22 Q. I mean, there's hundreds of 23 articles probably in here?</p> <p>24 A. It's a lot.</p>	<p style="text-align: center;">Page 273</p> <p>1 should know, in my opinion.</p> <p>2 Q. Doctor, what's your 3 understanding of whether or not --</p> <p>4 MR. BENTLEY: Let me rephrase 5 that.</p> <p>6 Q. What's your appreciation of when 7 a company such as Ethicon should introduce 8 changes to one of its marketed products? 9 Generally what's your standard?</p> <p>10 MR. ROSENBLATT: Object to form.</p> <p>11 Are you talking about the 12 design?</p> <p>13 BY MR. BENTLEY:</p> <p>14 Q. Do you understand my question?</p> <p>15 A. No.</p> <p>16 Q. If you want to turn to page 28. 17 You're talking about product design and 18 you start out "Due to the large volume." 19 Do you see that?</p> <p>20 A. Yes.</p> <p>21 Q. And you've testified that you've 22 consulted on product design with 23 companies, right?</p> <p>24 A. Correct.</p>

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<p>1 Q. And you have a sentence towards 2 the end you say: "Therefore, it was 3 appropriate for Ethicon to not introduce 4 changes to the mesh too rapidly."</p> <p>5 Do you see that?</p> <p>6 A. I see that.</p> <p>7 Q. And you've consulted with 8 companies on what changes to make to their 9 products; is that correct?</p> <p>10 A. That's correct.</p> <p>11 Q. And my question simply is what 12 is your standard for whether or not it's 13 appropriate to introduce changes? What's 14 your basis or your standard that you're 15 reaching this opinion?</p> <p>16 A. I don't think there's one 17 specific standard.</p> <p>18 I think it depends on what 19 change you're making, what modification 20 you're making, and when in the time frame 21 of the product where it was would affect 22 when you should make your changes.</p> <p>23 Q. And it sounds like you're 24 applying maybe a common sense standard</p>	<p>1 A F T E R N O O N S E S S I O N 2 BY MR. BENTLEY:</p> <p>3 Q. Doctor, we're back from a quick 4 lunch.</p> <p>5 Are you ready to go?</p> <p>6 A. Yes, I'm ready.</p> <p>7 Q. What suture material do you use, 8 generally?</p> <p>9 A. For what type of procedure?</p> <p>10 Q. For Burch procedure.</p> <p>11 A. 2-0 Gore-Tex are my suspension 12 sutures, but then I'll use other sutures 13 to close fascia, close skin.</p> <p>14 Q. We previously discussed that in 15 the late '90s, doctors were trying to use 16 Gore-Tex material for slings to treat 17 incontinence.</p> <p>18 Do you remember that?</p> <p>19 A. Yes, I do.</p> <p>20 Q. And those slings had poor 21 results; is that correct?</p> <p>22 A. Yes, the longer length slings.</p> <p>23 Q. So, just because you use a 24 Gore-Tex suture material today doesn't</p>
<p>1 based on your experience as a practicing 2 surgeon.</p> <p>3 Is that a fair summation of it?</p> <p>4 MR. ROSENBLATT: Object to form.</p> <p>5 A. That's the way -- you asked me 6 what my standard was. That's what mine 7 is.</p> <p>8 Q. I'm just trying to figure out 9 your basis for that.</p> <p>10 A. Yeah, that's okay.</p> <p>11 Q. You're not citing or referring 12 to any federal regulation there; is that 13 right?</p> <p>14 A. Yeah, I think a company can -- 15 is allowed to make changes when they want. 16 They just need to apply to the rules and 17 regulations.</p> <p>18 MR. BENTLEY: Off the record. 19 (Luncheon recess taken from 1:22 20 p.m. to 2:13 p.m.)</p> <p>21 - - -</p> <p>22</p> <p>23</p> <p>24</p>	<p>1 necessarily establish the safety and 2 efficacy of using Gore-Tex for a sling to 3 treat incontinence; is that correct?</p> <p>4 A. Yeah, they're different 5 materials that I'm using. But they're 6 also using them for different purposes.</p> <p>7 Q. Doctor, before we broke, we were 8 discussing the inflammatory response to 9 TVT and TVT-Exact once it's implanted.</p> <p>10 Do you remember that?</p> <p>11 A. Yes, I do.</p> <p>12 Q. And I believe you testified that 13 there's a chronic inflammatory response 14 and a transient inflammatory response?</p> <p>15 A. There's an acute and a chronic 16 one, is what I think I testified to.</p> <p>17 Q. You understand that the mesh 18 once implanted has a chronic inflammation 19 response that continues indefinitely?</p> <p>20 A. I think the fibers in the mesh 21 induce a chronic inflammatory response.</p> <p>22 Q. And that response is indefinite 23 while the mesh is implanted, correct?</p> <p>24 A. It's ongoing. Clinically we</p>
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<p>1 don't see an evidence, like evidence of an 2 inflammatory process going on in terms of 3 infection -- in terms of infectious areas, 4 fevers, erythema around those areas, but 5 yes, there is a long-term chronic 6 inflammatory response that occurs. 7 Q. So you wouldn't tell your 8 patients that TVT inflammatory reaction is 9 transient, would you?</p> <p>10 MR. ROSENBLATT: Object to form. 11 MR. BENTLEY: Let me rephrase 12 it.</p> <p>13 BY MR. BENTLEY:</p> <p>14 Q. When you consent your patients, 15 you provide them truthful and accurate 16 information, right?</p> <p>17 A. I try to.</p> <p>18 Q. Right. And if you were 19 discussing the inflammatory reaction that 20 can happen once the TVT mesh is implanted, 21 you wouldn't describe it as transient, 22 would you?</p> <p>23 A. Well, I wouldn't describe that 24 the chronic inflammatory reaction is</p>	<p>1 reaction is transient? 2 A. I'm aware of that. And my 3 understanding of that is that of the acute 4 inflammatory reaction that occurs whenever 5 you have an incision in surgery. 6 Q. And you understand that that 7 explanation is not provided in the IFU 8 though, right? 9 A. It's not explicitly written in 10 the IFU. 11 Q. Would you want to maybe provide 12 that better explanation in the IFU so it's 13 more clearly conveyed that there is indeed 14 a chronic inflammation response? 15 A. Once again, I would put in the 16 IFU what federal regulations require me to 17 put in. 18 Q. And you don't want to put 19 misleading information in the IFU, right? 20 A. Once again, I would put in the 21 what the federal regulations require. 22 Q. You can agree with me that the 23 federal regulations don't permit 24 misleading information, right?</p>
<p>1 clinically evident either. 2 Q. You would tell them there's a 3 chronic reaction -- 4 MR. BENTLEY: Strike that. 5 Q. You would tell your patients 6 there's a chronic inflammatory response 7 maybe in addition to the acute transient 8 response you were talking about? 9 A. No, I would tell my patients 10 that this is a permanent implant. Whether 11 or not they're going into inflammatory 12 responses would depend on their 13 questioning and what they -- how in-depth 14 they want to go on that. 15 Q. And in that discussion, if it 16 did go into the topics of inflammation, 17 you wouldn't describe it to your patients 18 as transient? 19 A. What I would describe is that 20 there's a chronic inflammatory process 21 that occurs with any type of implant that 22 is placed in the human body. 23 Q. And are you aware that the IFU 24 for TVT states that the inflammatory</p>	<p>1 Page 279 2 A. I would agree with you that 3 federal regulations don't want 4 misrepresentation of what's going on. 5 Q. So, to more clearly portray what 6 happens with the inflammatory response in 7 the body, if you're going to discuss the 8 inflammatory response in the IFU, you 9 would want to say that it's chronic, 10 correct? 11 MR. ROSENBLATT: Object to form. 12 A. No, I wouldn't. 13 I think that's pertaining to the 14 surgical procedure, what's mentioned in 15 the IFU. Any type of implant is going to 16 cause a chronic inflammatory reaction. 17 It's commonly known. 18 So why would I need to include 19 that in my IFU? 20 Q. Well, why would you say it's 21 transient in the IFU? 22 A. 'Cause I think they were trying 23 to explain to physicians about the process 24 of when you're putting it in and what happens when it's placed in.</p>

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<p>1 The IFU is never meant for 2 patients. It's meant for physicians. 3 Q. And you don't think that it's 4 more balanced to discuss the chronic 5 inflammatory response in addition to the 6 transient inflammatory response if you're 7 going to discuss the inflammatory response 8 in the IFU?</p> <p>9 A. Well, I think the acute 10 inflammatory response is clinically 11 evident. The patient may feel incisional 12 pain and may feel cramping pain. The 13 chronic inflammatory response is not 14 clinically evident.</p> <p>15 Q. So you don't think you should 16 put that in the IFU with the other 17 discussion to make it fair and balanced?</p> <p>18 A. Once again, it's not my opinion 19 that counts in the IFU. It's what the 20 federal regulations and guidelines require 21 in the IFU.</p> <p>22 Q. So, your opinion, Doctor, 23 generally your opinion is that the TTVT is 24 safe and effective; is that correct?</p>	<p>1 So I'm going to try to go to 2 fall back on the clinical literature to 3 see what the acceptable reoperation rates 4 or what the reoperation rates are with my 5 procedures now to try to come to a 6 determination of what it should be with a 7 TTVT or any kind of midurethral sling.</p> <p>8 Q. I need to nail this down, 9 Doctor.</p> <p>10 Based on your review of the 11 literature, and we need to know what 12 you're going to tell the jury. It's 13 important. And based on your extensive 14 review of the literature and 60 pages of 15 reports and countless articles, have you 16 come to a conclusion of what an acceptable 17 rate is for a reoperation for a 18 permanently implantable device used to 19 treat incontinence?</p> <p>20 A. So, I will base it on some of 21 the studies, the Canadian study that was 22 out there. I think somewhere between a 3 23 to 4 percent reoperation rates would be 24 acceptable.</p>
<p style="text-align: center;">Page 283</p> <p>1 A. That is correct.</p> <p>2 Q. And what do you consider as a 3 good efficacy rate for a product that's 4 implanted permanently to treat 5 incontinence?</p> <p>6 A. Well, I wish we could get to a 7 hundred percent, but I know that's not 8 realistic, and I think a product that 9 gives us about the 80 to 85 percent 10 success rate, and if we can get a little 11 higher to closer to 90 percent, and some 12 studies have shown that, would be a good 13 product.</p> <p>14 Q. Regarding a complication rate, 15 what would you consider an acceptable 16 reoperation rate for a permanent implant 17 that's used to treat incontinence?</p> <p>18 A. Well, that's going to depend on 19 the patient, as well as what the other 20 procedures that I have available to me 21 are.</p> <p>22 So, sometimes a 2 percent may be 23 acceptable, sometimes a 4 percent, 24 sometimes an 8 percent be acceptable.</p>	<p style="text-align: center;">Page 285</p> <p>1 Q. So something above that would be 2 unacceptable, using that standard?</p> <p>3 MR. ROSENBLATT: Object to form.</p> <p>4 A. I don't know if it would be 5 unacceptable. It's going to depend on the 6 patient. But if you're talking in 7 thousands of women, I think that those 8 numbers would be acceptable.</p> <p>9 Q. Okay. And similarly, what is 10 your opinion based on your review of the 11 literature and your experience of an 12 acceptable rate of erosion for a 13 permanently implantable mesh like the TTVT 14 and TTVT-Exact used to treat incontinence?</p> <p>15 A. I think the 2 percent erosion 16 rate that has been reported, the 17 approximate 2 percent erosion rate that's 18 been reported on TTVT is acceptable.</p> <p>19 Q. So using that standard, 20 something above 2 percent would be 21 unacceptable, in your opinion?</p> <p>22 A. Once again, it depends how far 23 above that 2 percent is there. So if 24 you're going to tell me 2.1 percent, I</p>

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<p>1 probably will say no, it doesn't matter. 2 If you're going to tell me 10 percent, 3 then I would consider it based on the 4 standard deviation and the statistics that 5 are provided to me.</p> <p>6 Q. And what is your definition of 7 what an acceptable rate of exposure is for 8 a permanently implantable device used to 9 treat stress urinary incontinence like TVT 10 and TVT-Exact?</p> <p>11 A. Well, I think you base the 12 standard rate based on the gold standard 13 right now.</p> <p>14 So my acceptable rate, if I had 15 a product that was higher than the TVT or 16 the midurethral sling, I would have to 17 fall back and say the TVT is the standard.</p> <p>18 Q. I need to know what your opinion 19 is as to what you think the exposure rate 20 is, and so I need to know what you think 21 the acceptable rate is.</p> <p>22 So my question is, Doctor, based 23 on your review of the literature and your 24 experience, what is an acceptable rate of</p>	<p>1 Can we find what that was? 2 Q. Well, that's the problem is 3 there's a number of studies cited in here 4 and there's no analysis from you. I don't 5 know what your opinion is.</p> <p>6 A. Okay.</p> <p>7 Q. What's your opinion based on the 8 literature and your experience of an 9 acceptable rate of erosion for a 10 permanently implantable device like the 11 TVT and TVT-Exact using your definition of 12 erosion that we had previously discussed?</p> <p>13 A. I would say it's .1 percent or 14 less would be acceptable.</p> <p>15 Q. And based on your review of the 16 literature as discussed in your report and 17 your experience, what is your definition 18 of an acceptable rate of de novo 19 dyspareunia after implantation of a 20 permanent device used to treat stress 21 urinary incontinence like the TVT and 22 TVT-Exact?</p> <p>23 MR. ROSENBLATT: Object to form. 24 When you're saying "acceptable,"</p>
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<p>1 exposure for a permanently implantable 2 device used to treat stress urinary 3 incontinence like TVT and TVT-Exact?</p> <p>4 A. In 2017 --</p> <p>5 MR. ROSENBLATT: Object to form.</p> <p>6 Q. You can answer.</p> <p>7 A. In 2017, I think a 2 percent 8 exposure rate is acceptable.</p> <p>9 Q. And just to clarify, your 2 10 percent exposure rate, is that you're 11 talking about external outside the body 12 exposure?</p> <p>13 A. Yes, I'm talking about an 14 exposure rate. I'm not talking about 15 total reoperation rate.</p> <p>16 Q. And your definition of an 17 acceptable erosion rate, that was talking 18 about internal organ perforation type 19 erosion; is that correct?</p> <p>20 A. There is -- yes, there is an 21 acceptable rate. That is even lower than, 22 I would say, what's the -- in my report, 23 we do have a number of the acceptable 24 rate.</p>	<p>1 do you mean what's commonly reported 2 in the literature or just his 3 personal?</p> <p>4 MR. BENTLEY: His report says 5 that it's 1 percent and it's 5 percent 6 and it's 15 percent. But he says it's 7 safe and based off of 50 different 8 numbers. I have no idea still exactly 9 what he thinks the rates are.</p> <p>10 MR. ROSENBLATT: I just can't 11 figure out if you're asking about what 12 he personally finds acceptable or 13 what's generally reported in the 14 literature.</p> <p>15 MR. BENTLEY: That's why I'm 16 saying based off his experience, what 17 is his rate.</p> <p>18 MR. ROSENBLATT: Okay.</p> <p>19 MR. BENTLEY: I'm just trying to 20 figure out what he thinks the rate is. 21 I don't know how else to.</p> <p>22 MR. ROSENBLATT: Got it.</p> <p>23 A. I understand. 24 I can tell you what I think the</p>

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<p>1 rate is in my hands for retropubic slings, 2 and what -- and with the retropubic sling, 3 I think the incidence of chronic pain and 4 dyspareunia is low. An acceptable rate 5 for me personally may be anywhere from, 6 for a retropubic sling anywhere between 2, 7 3, 4 percent.</p> <p>8 Q. For de novo dyspareunia, is your 9 testimony that an acceptable rate of 10 de novo dyspareunia for an implantable 11 permanent device to treat stress urinary 12 incontinence, your opinion is an 13 acceptable rate of de novo dyspareunia is 14 2 to 4 percent?</p> <p>15 A. I think it should be lower than 16 that, thinking of it that way. With the 17 retropubic sling, I don't think we see it 18 more than 1 to 2 percent to the time in my 19 personal experience. With some of the 20 other slings we may see it more.</p> <p>21 And it's also going to depend on 22 the patient population that you're 23 treating, if you're treating 24 post-menopausal or pre-menopausal patient</p>	<p>1 testifying of whether or not the 2 complication rates are higher than with 3 what was commonly known out there and what 4 the rates are as opposed to the absolute 5 rates of the surgical procedures.</p> <p>6 Q. Do you have an acceptable -- 7 Doctor, based on your literature review as 8 discussed in the TTVT and TTVT-Exact report 9 and based upon your clinical experience, 10 what is your opinion as to what is an 11 acceptable rate of chronic pain following 12 the implantation of a permanent medical 13 device, such as TTVT and TTVT-Exact, to 14 treat stress urinary incontinence?</p> <p>15 A. So, for this type of procedure, 16 I would like to see it around the 1 17 percent range, and I think that's what's 18 reported in the literature of chronic pain 19 at around the 1 percent range with the 20 retropubic sling. And sexual dysfunction 21 is probably reported at 0 to 1 percent, 22 but I'm not going to say there's 0 for 23 anything.</p> <p>24 Q. Okay. So, based off of the</p>
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<p>1 population.</p> <p>2 It's also going to depend on if 3 there's pre-existing dyspareunia as well 4 and what are the other factors that are 5 associated with it.</p> <p>6 It's hard to pin down an exact 7 number, and that's why a lot of these 8 studies don't give you that kind of exact 9 number. It's hard to get to.</p> <p>10 Q. Your answer, I think you said, 11 was 1 to 2 percent; is that correct?</p> <p>12 A. Personally, if my patients had a 13 higher than 1 to 2 percent rate and that's 14 what I was finding out, I would look to 15 see what is going on.</p> <p>16 Q. You understand that you're in 17 this litigation to give general causation 18 opinions about the device?</p> <p>19 A. Correct.</p> <p>20 Q. And you're being presented to 21 testify to the jury as to what your 22 opinions are regarding the complications 23 to TTVT and TTVT-Exact, right?</p> <p>24 A. My understanding is that I'm</p>	<p>1 rates we've just discussed, you would 2 agree that there's a wide range of 3 complication rates discussed in your 4 report for the TTVT and TTVT-Exact; is that 5 correct?</p> <p>6 A. Yeah, that's correct. Different 7 studies reported differently. So once 8 again --</p> <p>9 Q. And some studies may be above 10 and some may be below your acceptable 11 rates; is that fair?</p> <p>12 A. That's fair.</p> <p>13 Q. And based on your review of the 14 literature, these are the rates that you 15 determined are safe and acceptable; is 16 that correct?</p> <p>17 A. I think this is what occurs in 18 the literature.</p> <p>19 Q. And you didn't do any type of 20 systemic analysis to combine all of those 21 figures and run a meta-analysis to tell me 22 what the combination of all of that data 23 spits out as the actual rate, right?</p> <p>24 A. No, I didn't. I can base it on</p>

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<p>1 the clinical literature and my personal 2 experience seeing patients back for 3 follow-up, seeing them postsurgically, 4 seeing them in the years after, seeing 5 them in social situations, seeing them in 6 the hospital, and from my referring 7 physicians telling me how these patients 8 are doing, as well as colleagues who would 9 tell me if I -- if they had saw a patient 10 of mine with one of these complications. 11 Q. And is that the extent of the 12 basis? 13 A. The clinical -- the literature 14 and my clinical experience, yes. 15 Q. Doctor, you would agree that 16 different slings manufactured by different 17 companies have different efficacy rates 18 and complication rates, wouldn't you? 19 A. Different slings can have 20 different efficacy rates and complication 21 rates, yes. 22 Q. And one of the things you're 23 going to look at is ultimately the quality 24 of life after the implant procedure for</p>	<p>1 identification, as of this date.) 2 BY MR. BENTLEY: 3 Q. This is a study by you from 2011 4 that was published in the International 5 Journal of Gynecology and Obstetrics, 6 correct? 7 A. Correct. 8 Q. And the title of the study is 9 "Comparison of quality-of-life changes in 10 patients with stress urinary incontinence 11 after midurethral sling placement." 12 Correct? 13 A. Correct. 14 Q. And in this study, you evaluated 15 the Ethicon Retropubic TVT versus the AMS 16 SPARC; is that correct? 17 A. Correct. This particular data 18 was from a patient population from Dr. 19 Klapper. I did work on the study, but it 20 was not patients that I operated on. 21 Q. And your name's on the study, 22 right? 23 A. Yeah. I participated in the 24 study. There's no question about it.</p>
<p>1 the patient? 2 A. That's one of the things that we 3 looked at for outcomes is quality of life, 4 correct. 5 Q. That's an important measure? 6 A. It is one of the important 7 measures. 8 Q. And you've, in fact, studied 9 whether there is a difference between 10 different slings made by different 11 companies on patient quality of life, 12 right? 13 A. There are studies out there 14 comparing slings, yes. 15 Q. You have actually done those 16 studies, right? 17 A. I did those studies. 18 I'm trying to recall which one 19 in particular you're talking about. So I 20 can get to my CV and we'll take a look. 21 Q. I'm going to hand you what is 22 being marked as 26. 23 (Exhibit Winkler 26, Shalom 24 article, was marked for</p>	<p>1 Q. It's a good study in a reputable 2 journal, right? 3 A. I'm just telling you I didn't 4 operate on these patients. 5 Q. And this study found that there 6 was a difference in quality of life 7 between the AMS sling and the Ethicon 8 sling, right? 9 A. Let me just read it over again. 10 It's been a while since I've looked at 11 this study. 12 Well, the UDS scores for the 13 suprapubic versus transvaginal were the 14 same. Postoperative patients underwent a 15 super -- yes, so the UDI-6 scores for the 16 transvaginal procedure were lower in this 17 study. 18 Q. And in the last page, actually 19 the conclusion that you put, you and the 20 other authors on this article conclude: 21 "However, improvements in UDI-6 quality of 22 life scores was significantly better in 23 the suprapubic group." 24 And that's the AMS device,</p>

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<p>1 right?</p> <p>2 A. That's the AMS device, the</p> <p>3 SPARC, yes.</p> <p>4 Q. In this same column at the top,</p> <p>5 you and the authors hypothesized that the</p> <p>6 difference in diameter of the trocars may</p> <p>7 have affected the quality of life; is that</p> <p>8 correct?</p> <p>9 A. Can you show me where that is?</p> <p>10 Q. Sure.</p> <p>11 At the top you put: "There are</p> <p>12 subtle differences between suprapubic and</p> <p>13 the transvaginal instruments used for" --</p> <p>14 A. Yes, so that was a hypothesis</p> <p>15 back in 2011. Today I would base my</p> <p>16 opinions and conclusions on Cochrane</p> <p>17 reviews, which is higher level evidence</p> <p>18 than my paper back then, stating that the</p> <p>19 transvaginal approach is better. It has a</p> <p>20 slightly higher objective rate than the</p> <p>21 suprapubic approach. And clinically, my</p> <p>22 patient population, I did see good results</p> <p>23 with the transvaginal approach, and that's</p> <p>24 why I continued with it.</p>	<p>1 Do you see that? It's in that</p> <p>2 top right paragraph.</p> <p>3 A. Yes, I do. And that would be on</p> <p>4 acute inflammation and acute tissue</p> <p>5 injury.</p> <p>6 Q. So maybe reducing the trocar</p> <p>7 diameter could be a little bit safer, is</p> <p>8 that what this is finding?</p> <p>9 A. That reducing the trocar</p> <p>10 diameter may give you a slightly better</p> <p>11 result, yes.</p> <p>12 Q. By better, safer, less</p> <p>13 morbidity, right?</p> <p>14 A. Well, the quality of life is not</p> <p>15 a morbidity question. Quality of life is</p> <p>16 how patients are feeling and how much it's</p> <p>17 bothering them.</p> <p>18 Q. I appreciate that.</p> <p>19 The difference in diameter may</p> <p>20 result in a more limited dissection,</p> <p>21 right?</p> <p>22 A. Correct.</p> <p>23 Q. Which could be safer, right?</p> <p>24 A. I wouldn't want to use "safer"</p>
<p style="text-align: center;">Page 299</p> <p>1 Q. And in this published article</p> <p>2 though, you note that the quality of life</p> <p>3 was improved in the AMS device, right?</p> <p>4 A. Correct.</p> <p>5 Q. And one of the differences with</p> <p>6 the AMS device is it has that 3 millimeter</p> <p>7 trocar compared to the Ethicon TVT which</p> <p>8 is 5 millimeter trocar, right?</p> <p>9 A. In 2011 I had already converted</p> <p>10 away from the Ethicon larger trocar.</p> <p>11 Q. And in this article you found</p> <p>12 that there was a difference in quality of</p> <p>13 life, right?</p> <p>14 A. Correct.</p> <p>15 Q. And you hypothesized that maybe</p> <p>16 it was due to the diameter in trocar,</p> <p>17 right?</p> <p>18 A. There were subtle differences,</p> <p>19 so we said that that may be one of the</p> <p>20 reasons, correct.</p> <p>21 Q. And you explain that the</p> <p>22 differences in diameter may result in a</p> <p>23 more limited dissection and a resulting</p> <p>24 tissue injury or inflammation.</p>	<p style="text-align: center;">Page 301</p> <p>1 'cause I don't think that one -- the</p> <p>2 larger needles or the smaller needles</p> <p>3 have -- one has been proven to be safer</p> <p>4 than the other. This is a hypothesis over</p> <p>5 here, but I'm not aware of any clinical</p> <p>6 data saying that the -- there were more --</p> <p>7 one was safer than the other.</p> <p>8 Q. Just the patients had better</p> <p>9 quality of life with the smaller needle;</p> <p>10 whether or not that was the cause, you</p> <p>11 don't know?</p> <p>12 A. Correct. It's an hypothesis.</p> <p>13 Q. And you don't discuss this</p> <p>14 article in your report.</p> <p>15 Is there any reason for that?</p> <p>16 A. I don't think this article is on</p> <p>17 the safety and efficacy of the TTV. It</p> <p>18 just shows us one component.</p> <p>19 And like I said, there's much</p> <p>20 better data out there than this study,</p> <p>21 fortunately, to substantiate my claims in</p> <p>22 my report.</p> <p>23 Q. And the TTV's a kit that's sold,</p> <p>24 right?</p>

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<p>1 A. Yeah, I guess you can call it a 2 kit.</p> <p>3 Q. Well, the TVT actually includes 4 the trocars, right?</p> <p>5 A. Well, the TVT included the 6 trocar, I guess the T part in the TVT, 7 that was reusable. You know, the handle 8 part, the Mickey Mouse handle part.</p> <p>9 Q. That would be TVT disposable. 10 But I think TVT comes with the 11 trocars, right?</p> <p>12 MR. BENTLEY: Let me rephrase 13 that.</p> <p>14 Q. Ethicon provides the trocars for 15 the TVT, right?</p> <p>16 A. Yeah, but there was a reusable 17 device that screwed on to the TVT-R.</p> <p>18 Q. Right.</p> <p>19 A. That you -- that was reusable. 20 That wasn't in the kit.</p> <p>21 Q. Who designs and manufactures 22 those?</p> <p>23 A. Ethicon, J&J. 24 But I'm just saying that wasn't</p>	<p>1 Q. And part of the way we've 2 defined it today is safety, or your 3 analysis of safety is based upon the 4 relative safety of this device versus 5 alternative procedures and devices, right?</p> <p>6 A. Correct.</p> <p>7 Q. Because there's no absolute a 8 hundred percent safe?</p> <p>9 A. No. Don't have surgery if 10 you're looking for a hundred percent of 11 anything.</p> <p>12 Q. And we discussed that you are 13 relying upon other people's systematic 14 reviews and meta-analysis, right?</p> <p>15 A. I'm relying on them as well as 16 my clinical experience.</p> <p>17 Q. Because we're not doing 18 statistical analysis here. That's someone 19 else's expertise, right?</p> <p>20 A. When I reviewed a paper, I did 21 not do a statistical analysis. I will try 22 to review the statistics, but I'm not 23 doing a breakdown of the analysis each 24 time.</p>
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<p>1 part of the kit.</p> <p>2 Q. The trocar design was made by 3 Ethicon, right?</p> <p>4 A. The trocar design was made by 5 Ethicon. That particular part of it was a 6 reusable part, so it wasn't in each and 7 every kit.</p> <p>8 Q. I think I understand, your 9 opinion is that the TVT and TVT-Exact are 10 safe because they're safer than some of 11 the other procedures? Is that generally 12 it?</p> <p>13 A. I think they are -- are a safe 14 procedure, yes.</p> <p>15 Q. And we're having a difficulty 16 defining numerically what safe is, and I 17 think that it's a relative analysis; is 18 that correct?</p> <p>19 A. Right. I think everyone's going 20 to decide what safe is and some patients 21 may consider one in a hundred safe, one in 22 a thousand safe, one in ten thousand safe. 23 So it's a really hard number to, or hard 24 word to explicitly define -- define.</p>	<p>1 Q. If you could please turn to page 2 52. At the top of the page you're 3 discussing the Schimpf 2014 meta-analysis 4 review of RCTs.</p> <p>5 Do you see that?</p> <p>6 A. Yes, I do.</p> <p>7 Q. And that's what we discussed 8 was -- on page 52 of your report you're 9 talking the Schimpf meta-analysis.</p> <p>10 Do you see that?</p> <p>11 A. Yes, I do.</p> <p>12 Q. And you note that the Schimpf 13 meta-analysis which reflected RCTs with at 14 least 12 month follow-up, that --</p> <p>15 A. That's accurate.</p> <p>16 Q. And is 12 month follow-up 17 important to you to note that here?</p> <p>18 A. Well, I don't think if you're -- 19 looking at data today, you wouldn't want 20 to look at any data less than 12 months, 21 for what's available.</p> <p>22 Q. Because most of the 23 complications occur within the first 12 24 months, right?</p>

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<p>1 A. Yes. Many of the -- the 2 majority of complications will usually 3 occur in the first 12 months.</p> <p>4 Q. So this meta-analysis limited 5 their review to RCTs, which are randomized 6 control trials, right?</p> <p>7 A. Yes.</p> <p>8 Q. They have at least 12 month 9 follow-up, so they're going to hopefully 10 capture the majority of the complications 11 right?</p> <p>12 A. Well, there was at least 13 12-month follow-up, so there's follow-up 14 that's longer in there as well.</p> <p>15 Q. Even better, right?</p> <p>16 A. Correct.</p> <p>17 Q. And you note that they found 18 comparing midurethral slings to Burch 19 there's no difference in objective or 20 subjective cure, quality of life, or 21 sexual function to outcomes.</p> <p>22 Do you see that?</p> <p>23 A. Yes, I do.</p> <p>24 Q. And these authors, after</p>	<p>1 or erosion and OAB symptoms."</p> <p>2 Is that correct?</p> <p>3 A. Yeah.</p> <p>4 So, slings, whether it's a 5 synthetic sling or a pubovaginal sling, 6 have a higher risk of voiding dysfunction 7 or obstruction, so that's why it's going 8 to be a higher chance for those patients 9 to go back to the operating room to 10 release or cut the slings and there is 11 no -- there's less risk of exposure or the 12 incidence of exposure with a Burch 13 procedure in lower than with the sling 14 procedure. So it's not surprising that 15 patients went to the back operating room 16 for that.</p> <p>17 Q. So, the Burch was as effective 18 as the slings, right?</p> <p>19 A. Yes.</p> <p>20 Q. And slings had a higher rate of 21 reoperation -- and the slings had a higher 22 rate of reoperation as compared to the 23 Burch, right?</p> <p>24 A. That's not what I said. And if</p>
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<p>1 reviewing RCTs with at least 12-month 2 follow-up, found that there was really no 3 difference.</p> <p>4 Do you have some criticism or 5 critique of their findings?</p> <p>6 A. I do not have criticism. I have 7 never once stated that a Burch is a bad 8 procedure. A Burch has a good outcome. 9 However, there's increased morbidity 10 associated with the procedure as compared 11 to midurethral slings.</p> <p>12 Q. And here they're saying it has 13 the same efficacy, right?</p> <p>14 A. That's a good thing.</p> <p>15 Q. Right?</p> <p>16 A. (No verbal response.)</p> <p>17 Q. And they note that with respect 18 to complications, the slings have a lower 19 rate of short-term complications compared 20 to Burch, right?</p> <p>21 A. Yes, they do.</p> <p>22 Q. But you state: "Not surprisingly, 23 the slings had a higher rate of long-term 24 return to the operating room for retention</p>	<p>1 you read the next line: "However, their 2 studies did not consider patients to 3 return to the operating room for prolapse 4 which occurs in 13.6 of patients who 5 undergo a Burch procedure."</p> <p>6 So, they didn't include in the 7 study in their Burch patients the number 8 of patients that had to go back to the 9 operating room for a different reason. 10 So, I'm just saying it's a little hard to 11 make that comparison of reoperation rates.</p> <p>12 Q. Are you saying that the 13 development of prolapse is a complication 14 of the Burch?</p> <p>15 A. Prolapse can happen after the 16 Burch procedure, yes. And that's a known 17 common complication. And it's 18 hypothesized that you're lifting up that 19 anterior vaginal wall, there's more 20 pressure going posteriorly, so causing an 21 enterocele and prolapse.</p> <p>22 Q. And can prolapse happen after a 23 sling procedure?</p> <p>24 A. It's a different type of</p>

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<p>1 procedure and we're not -- it can happen, 2 but there's no causality that people have 3 hypothesized that it's coming from the 4 sling procedure.</p> <p>5 Q. So --</p> <p>6 A. They're different operations.</p> <p>7 Q. I'm just trying to understand 8 how you've incorporated this meta-analysis 9 that use RCTs with 12-month follow-up that 10 appears to have findings not supportive of 11 your opinion. I'm trying to understand 12 why you discounted that.</p> <p>13 A. No, it's totally supportive of 14 my opinion. I think you're misreading it.</p> <p>15 I'm just saying that they didn't 16 consider this component in their analysis 17 of what they were comparing reoperation 18 rates.</p> <p>19 Q. So this found there was a higher 20 reoperation rate with slings, right?</p> <p>21 A. Yes, for these problems, for 22 retention, erosion and OAB. And my 23 understanding is they didn't include 24 patients who had to go back to the</p>	<p>1 retention, OAB symptoms, shorter operating 2 time and hospital stay.</p> <p>3 I'll read on.</p> <p>4 Q. No, hold on.</p> <p>5 The fact that they had less 6 blood loss, that's important to you?</p> <p>7 A. Yes.</p> <p>8 Q. The fact that they had a shorter 9 operating time, that's important to you?</p> <p>10 A. Yes, that's the benefit to the 11 patient. Less blood loss, shorter 12 operating time is a benefit to the 13 patient.</p> <p>14 Q. Less obstruction is important, 15 right?</p> <p>16 A. Correct.</p> <p>17 Q. And less transfusions, right?</p> <p>18 A. Correct.</p> <p>19 Q. Those are all important 20 indicators of -- to take into account when 21 you're deciding whether or not to undergo 22 a procedure, right?</p> <p>23 A. Those are all components of 24 morbidity.</p>
<p style="text-align: center;">Page 311</p> <p>1 operating room for prolapse that develops 2 after a Burch procedure. That's all I'm 3 saying.</p> <p>4 Q. Is that your one criticism or 5 critique of --</p> <p>6 A. That's the one that I wrote. If 7 we want to go through line-by-line for the 8 article.</p> <p>9 Q. Well, today is I've got to learn 10 all of the bases for why you're 11 discounting the study.</p> <p>12 A. I'm not discounting it. All I'm 13 saying is that is one thing they did not 14 consider.</p> <p>15 I wouldn't discount an entire 16 study based on one thing.</p> <p>17 Q. Help me explain why is this 18 study supportive of your opinion then?</p> <p>19 A. Well, it says a couple of things 20 over here. That subjective cure outcomes 21 of TVT versus pubovaginal vaginal slings 22 after TVT. Retropubic slings had less 23 blood -- retropubic slings had less blood 24 loss, transfusions, wound infections,</p>	<p style="text-align: center;">Page 313</p> <p>1 Q. And that was a comparison 2 between TVT and pubovaginal slings, right?</p> <p>3 A. Correct.</p> <p>4 Q. And then comparing the 5 midurethral slings to Burch, there was no 6 objective or subjective cure, quality of 7 life, or sexual function outcomes, right?</p> <p>8 A. Correct, and I think that's an 9 important statement.</p> <p>10 Q. That it's the Burch and the TVT 11 are essentially the same for efficacy and 12 for those outcomes?</p> <p>13 A. For those -- yes, for those 14 outcomes.</p> <p>15 Q. But retropubic slings had a 16 higher rate of reoperation than Burch, 17 right?</p> <p>18 A. So, that's where my criticism 19 comes in because we don't know the total 20 reoperation rate for patients with Burches 21 because they didn't include the patients 22 who may have gone back to the operating 23 room for prolapse.</p> <p>24 Q. At the bottom of that page,</p>

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<p>1 Doctor, you note that "As a testament to 2 safety and efficacy." 3 Do you see that paragraph? 4 A. Yes. 5 Q. You end that paragraph with: 6 "The FDA is not requiring any further 7 studies for the TVT sling to support its 8 user safety." 9 Do you see that? 10 A. Correct. 11 Q. That's part of your explanation 12 as a testament to the safety and efficacy? 13 A. Yeah, and if I remember 14 correctly, what the FDA, don't point me, 15 came out in their 2013 statement saying 16 that there was a safety and efficacy to 17 support the use of the full-length slings. 18 Q. I think I understand. 19 So, you say: "As a testament to 20 the safety and efficacy," and you're 21 discussing the TVT slings, right? 22 A. Correct. 23 Q. And one of the bases for your 24 opinion that they're safe and effective is</p>	<p>1 there's also not a production of 2 internal documents associated with Dr. 3 Winkler that we still have not 4 adequately necessarily reviewed. If 5 anything else pops up, we reserve our 6 right to come back. 7 MR. ROSENBLATT: Objection 8 noted. 9 I would just like to say for the 10 record the flash drive that we 11 provided you is consistent with the 12 materials obtained -- that you can 13 find on the reliance list that was 14 produced with his report. 15 Additionally, we are under no 16 obligation to hand you on a platter 17 every single produced document that 18 references Dr. Winkler. You guys have 19 access to those documents. 20 We have objected to your 21 document requests, and we'll object to 22 any deposition outside of today. 23 MR. BENTLEY: And just to 24 clarify regarding the objections to</p>
<p>1 the FDA has not required further studies 2 of the TVT sling for support -- to support 3 its use or safety; is that correct? 4 A. Correct. 5 And we discussed the 522 studies 6 which you asked me about prior. 7 MR. BENTLEY: Thank you, Doctor. 8 That's all I have for right now. 9 THE WITNESS: Okay. 10 MR. BENTLEY: For those 11 products. 12 THE WITNESS: I figured that 13 much. 14 MR. BENTLEY: For the record, 15 plaintiffs are moving to keep the 16 deposition open pending review of the 17 production materials that were 18 produced prior to this deposition, it 19 was that thumb drive with extensive 20 materials on it that we haven't had a 21 full opportunity to review. Should we 22 find something that is important, we 23 reserve our right to come back. 24 And it's our understanding</p>	<p>1 the notice, there was a couple of RFPs 2 where they were simply objected to and 3 Ethicon did not state that it was 4 producing any responsive documents. 5 They were standing on the objections. 6 And it's our contention that there's 7 clearly relevant and responsive 8 material that we need in preparation 9 for this deposition that we may not 10 have found, and if it's in the 11 database, we would reserve our right. 12 Thank you. 13 MR. ROSENBLATT: Okay. We'll 14 maintain our objections to that, but 15 your objection is noted. 16 EXAMINATION BY 17 MR. ROSENBLATT: 18 Q. Dr. Winkler, thank you for being 19 with us today. 20 My name is Paul Rosenblatt. I 21 represent Ethicon Inc. and Johnson & 22 Johnson. 23 Doctor, you recall being asked 24 some questions about your CV?</p>

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<p>1 A. Yes, I do.</p> <p>2 Q. That was marked as Exhibit 3.</p> <p>3 Do you have that in front of</p> <p>4 you?</p> <p>5 A. I will try get that.</p> <p>6 Yes, I got it.</p> <p>7 Q. On page 7 of your CV, you list</p> <p>8 some of the national and international</p> <p>9 courses or presentations that you've</p> <p>10 given.</p> <p>11 Is that accurate?</p> <p>12 A. That is accurate.</p> <p>13 Q. And if it's possible that there</p> <p>14 may be a presentation or a professional</p> <p>15 education event, such as a cadaver lab or</p> <p>16 a preceptorship, that does not appear on</p> <p>17 this list, did you leave any out</p> <p>18 intentionally?</p> <p>19 A. I didn't leave anything out</p> <p>20 intentionally. There's always a</p> <p>21 possibility that things were left out.</p> <p>22 I had to go back in -- in 2011</p> <p>23 to 2012 to try to figure out what courses</p> <p>24 I've taught where and when, and it was not</p>	<p>1 I've had exposure to throughout the</p> <p>2 year -- years.</p> <p>3 Q. And on page 6 of your report,</p> <p>4 you list some additional teaching</p> <p>5 experience; is that fair?</p> <p>6 A. Page 6 of my CV?</p> <p>7 Q. Correct.</p> <p>8 A. Yes. So, like I said, I tried</p> <p>9 to piecemeal together the early stuff that</p> <p>10 I did. Most of the early stuff that I did</p> <p>11 I tried -- you're going to see it's mostly</p> <p>12 local stuff. There's very little national</p> <p>13 or international stuff early on in my</p> <p>14 career. These were weekends that I took</p> <p>15 off, days that I took off from work, days</p> <p>16 that I was out of the office, days that I</p> <p>17 was away from my family. I did mostly</p> <p>18 grand rounds back then to try to help</p> <p>19 build my career and reputation and inform</p> <p>20 other people. But it was time away either</p> <p>21 from the office or the family.</p> <p>22 Q. So if you received an honorarium</p> <p>23 from whoever was sponsoring the event,</p> <p>24 whether it was AMS or whoever, would that</p>
<p>1 an easy task to piece together.</p> <p>2 Q. And you're certainly not trying</p> <p>3 to hide in your CV that you might have had</p> <p>4 some affiliations with industry in the</p> <p>5 past; is that fair?</p> <p>6 A. I don't hide it. I think I</p> <p>7 mention it in my reports as well.</p> <p>8 I believe that physicians need</p> <p>9 to work with industry as opposed to be</p> <p>10 enemies with industry.</p> <p>11 Q. Doctor, if you turn to page 8,</p> <p>12 it says: "Mentoring of graduate students,</p> <p>13 residents, postdoctoral fellows and</p> <p>14 research."</p> <p>15 Are these all of the graduate</p> <p>16 students, residents and fellows that</p> <p>17 you've taught throughout your career?</p> <p>18 A. These are not at all all of them</p> <p>19 that I've taught. This is just a</p> <p>20 representation of residents that have</p> <p>21 decided to go into or attempt to go into</p> <p>22 female pelvic medicine who I had a closer</p> <p>23 relationship with as opposed to the</p> <p>24 hundreds and hundreds of residents that</p>	<p>1 honorarium, or would you have been doing</p> <p>2 that speaking event for the purposes of</p> <p>3 getting that honorarium?</p> <p>4 A. No, I wouldn't do it for the</p> <p>5 honorarium.</p> <p>6 And back then, you know, things</p> <p>7 were different than they are today. So,</p> <p>8 today you would get your honorarium from</p> <p>9 the hospital that you were doing the grand</p> <p>10 rounds in. Back then, you may have gotten</p> <p>11 your honorarium from a company supporting</p> <p>12 it.</p> <p>13 So, the -- the relationship that</p> <p>14 industry has with physicians and the</p> <p>15 relationship that industry has with</p> <p>16 hospitals has evolved over time.</p> <p>17 Q. And for example, Doctor, if you</p> <p>18 turn to page 9 of your CV, you list some</p> <p>19 of the contracts, grants and sponsored</p> <p>20 research.</p> <p>21 Do you see that?</p> <p>22 A. Yes, I do.</p> <p>23 Q. If you go through page 9, 10,</p> <p>24 11, and 12, it lists various grants,</p>

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<p>1 predominantly sponsored by industry; is 2 that fair? 3 A. That is fair. 4 And once again, I feel that we 5 need to work with industry in order to 6 meet our goal, improve patients' lives, 7 improve safety and efficacy of products 8 and to learn about products. It's 9 expensive to run these studies, and 10 institutions just don't have that kind of 11 money sometimes. 12 Q. Just taking one, for example, on 13 page 9 it says AMS and then \$29,000, 14 essentially. 15 Would that be money that's paid 16 to you that goes into your pocket? 17 A. Absolutely not. None of this 18 money goes into my pocket anywhere, 19 actually. This money goes into a -- to a 20 hospital fund, and we've been trying to 21 restrict any money that we make on a grant 22 to promote further research. 23 Q. So, if it were suggested at 24 trial that you've been paid X-number of</p>	<p>1 journal articles for years. I've written 2 journal articles with residents and 3 fellows and myself throughout the last 20 4 years. 5 Q. What are some of the editorial 6 positions that you've had that are listed 7 on page 5 of your CV? 8 A. So, I've been a reviewer for the 9 International Urogynecology Journal of 10 Female Pelvic Medicine and Reconstructive 11 Surgery. I've done journal reviews for 12 the American Journal of Obstetrics and 13 Gynecology, and I've also been -- I was an 14 abstract reviewer, I guess for not this 15 past one, but the previous AUGS meeting. 16 Q. Doctor, I want to show you your 17 reliance list. 18 Do you see I think it's the 19 fourth page from the end where it says "21 20 CFR 801.109(c) Device Labeling"? 21 A. Yes, I do. 22 Q. When you referenced the CFR that 23 you relied upon, is that, in fact, the 24 specific section that you relied upon?</p>
<p>1 dollars from industry based on the 2 calculation of pages 9 to 12, would that 3 be accurate or inaccurate? 4 MR. BENTLEY: Objection; 5 outside the scope; leading; 6 compound. 7 A. This is inaccurate. Anything 8 that was paid over here would have been 9 paid to the hospital, and it will -- like 10 for instance, if you go on the government 11 Web site today, there is going to be a 12 differentiation of money that I received 13 to my pocket or money that I received for 14 research dollars. And we didn't have that 15 kind of strict rules back then, but this 16 is all money that went to the hospital. 17 Q. Doctor, just looking at your 18 list of publications, would it be fair to 19 say that you have extensive experience 20 publishing on treatments for stress 21 urinary incontinence? 22 A. I have extensive experience on 23 that. I've been reviewing journal 24 articles for years. I've peer-reviewed</p>	<p>1 A. Yes, it is. 2 Q. Even though that is a specific 3 section, have you in fact read the entire 4 CFR related to, or at least skimmed the 5 CFR related to device labeling? 6 A. Yes, I have. 7 THE WITNESS: Could we go off 8 the record for a second? 9 (Discussion held off the record.) 10 BY MR. ROSENBLATT: 11 Q. Doctor, you were asked some 12 questions about Burch and autologous 13 fascial slings. 14 Do you recall those questions? 15 A. Yes, I do. 16 Q. If someone were to suggest that 17 currently the Burch or the autologous 18 fascial sling is the current gold standard 19 treatment for uncomplicated stress urinary 20 incontinence, would that be accurate? 21 A. It is not. I would disagree 22 with that statement. It is not the 23 current gold standard. 24 The current gold standard, as</p>

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<p>1 noted in multiple publications, as well as 2 reviews, is the midurethral sling. 3 Q. I want to jump around a little 4 out of order, Doctor. 5 A. No problem. 6 Q. You were asked some questions 7 about frequency and severity of 8 complications. 9 A. Yes. 10 Q. I believe you testified that you 11 primarily rely upon the Level I medical 12 literature for that information? 13 A. Yes, I do. 14 Q. Do you know if that's the 15 general practice of surgeons in your 16 field? 17 A. It is the general practice to 18 rely on the highest quality data that's 19 available.</p> <p>20 MR. ROSENBLATT: Do you have the 21 exhibit stickers? 22 (Exhibit Winkler 27, Unger 23 article, was marked for 24 identification, as of this date.)</p>	<p>1 "Indications and Risk Factors For 2 Midurethral Sling Revision." 3 Do you see that? 4 A. Yes, I do. 5 Q. And they noted in the conclusion 6 the rate of sling revision after 7 midurethral sling placement was 2.7 8 percent? 9 A. I see that and I agree with 10 that, correct. 11 Q. And this was based on over 3,000 12 women? 13 A. Who underwent the sling, yes. 14 Q. So, do you rely on literature 15 such as the Unger study to get a better 16 understanding as to what the overall 17 expected and acceptable revision rates are 18 for midurethral slings? 19 A. Yes, it's one of the studies 20 that I would rely on. 21 (Exhibit Winkler 28, Welk 22 article, was marked for 23 identification, as of this date.)</p>
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<p>1 BY MR. ROSENBLATT: 2 Q. You were asked some questions 3 about reoperation rates. 4 Do you recall those questions? 5 A. Yes, I do. 6 Q. I'm marking Exhibit 27. 7 MR. BENTLEY: Do you have a 8 copy? 9 MR. ROSENBLATT: I've got them 10 here (indicating). 11 MR. BENTLEY: Do you want to 12 pull it out, or can I look at the 13 binder or something? I don't have it 14 necessarily. 15 MR. ROSENBLATT: Go off the 16 record a second. 17 (Discussion held off the record.) 18 BY MR. ROSENBLATT: 19 Q. Doctor, I've just handed you 20 Exhibit 27. 21 Is this a study that was 22 referenced in your report? 23 A. Yes, it is. 24 Q. And it's by Unger titled</p>	<p>1 BY MR. ROSENBLATT: 2 Q. I'll hand you what I've marked 3 as Exhibit 28 which is a study by Welk 4 titled "Removal and Revision of Vaginal 5 Mesh Use For the Treatment of Stress 6 Urinary Incontinence." 7 Do you see that? 8 A. Yes, I do. 9 Q. Is this also a study that was 10 referenced in your report? 11 A. Yes, it is. 12 Q. You'll see that they noted: 13 "Complications were treated in 1,307 women 14 at a rate of 2.2 percent." 15 A. Yes, I see that. 16 Q. And the 10-year cumulative 17 incidence rate was 3.29. 18 A. I see that. 19 Q. And that the conclusion states: 20 "10 years after SUI surgery, 1 of every 30 21 women may require a second procedure for 22 mesh removal or revision." 23 Do you see that? 24 A. Yes, I do.</p>

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<p>1 Q. And that: "Patients of lower 2 volume surgeons have a 37 percent 3 increased likelihood of having a 4 complication."</p> <p>5 Do you see that?</p> <p>6 A. I do see that.</p> <p>7 This is what I based some of my 8 experience with, the literature that is 9 out there of the 1 in 30. However, I'm a 10 higher-volume surgeon who does many of 11 these procedures. So in my clinical 12 experience and my follow-up, we've seen a 13 slightly lower rate.</p> <p>14 Q. What does that indicate to you 15 as to whether or not the mesh of TVT or 16 midurethral slings is defective based on 17 there being a difference between 18 high-volume versus low-volume surgeon?</p> <p>19 MR. BENTLEY: Objection.</p> <p>20 A. I don't think it's defective on 21 the product at all. I think it's based on 22 the decision process of who may be getting 23 a sling. I think it may be based on the 24 decision of what type of sling was placed,</p>	<p>1 comes into play, postmenopausal, older 2 woman. All these things have to factor in 3 when you're having a discussion with a 4 patient of acceptable surgical risks.</p> <p>5 Q. And so, if a patient had 6 dyspareunia before a midurethral sling 7 procedure and then had dyspareunia after a 8 midurethral sling procedure, would that 9 indicate that the sling is defective just 10 because the patient continued to have 11 dyspareunia?</p> <p>12 A. Absolutely not. The patient had 13 dyspareunia. And there's some data to 14 support that patients who have chronic 15 pain-type syndromes may have more 16 complications than patients who do not, 17 and that's something that we would discuss 18 with patients as well.</p> <p>19 Q. Doctor, I want to refer you to 20 what I've marked as Exhibit 29. 21 (Exhibit Winkler 29, Guideline 22 for the Surgical Management of Female 23 Stress Urinary Incontinence: 2009 24 Update, was marked for identification,</p>
<p>1 and on the tissue quality, most 2 importantly, of some of these patients, as 3 well as the dissection that's performed by 4 these surgeons.</p> <p>5 Q. You were asked a lot of 6 questions about what you considered to be 7 acceptable complication rates.</p> <p>8 Do you see those?</p> <p>9 A. Yes, I do.</p> <p>10 Q. If a study showed a slightly 11 higher rate based on the ones that you 12 discussed, would you automatically 13 consider that to be unacceptable?</p> <p>14 A. Absolutely not. And once again, 15 it always depends on what those 16 complications are and what are we talking 17 about. It all needs to be taken in 18 context as opposed to just the number.</p> <p>19 Q. So for example, are there 20 different patient types that might be more 21 prone to a complication, such as a smoker 22 versus a non-smoker?</p> <p>23 A. Yes, a smoker, somebody who may 24 be on chronic steroids, or age sometimes</p>	<p>1 as of this date.)</p> <p>2 BY MR. ROSENBLATT:</p> <p>3 Q. This is the AUA Guideline For 4 the Surgical Management of Female Stress 5 Urinary Incontinence: 2009 Update.</p> <p>6 A. Yes.</p> <p>7 Q. It shows that it's revised in 8 2012.</p> <p>9 A. Yes.</p> <p>10 Q. Doctor, if you look on the 11 second to last page under "Slings 12 synthetic at midurethra" in the middle 13 column.</p> <p>14 A. Yes.</p> <p>15 Q. And you go down to "Subjective 16 Complaints," what is listed for pain?</p> <p>17 A. One percent.</p> <p>18 Q. What is listed for sexual 19 dysfunction?</p> <p>20 A. Zero percent.</p> <p>21 Q. What is listed for voiding 22 dysfunction?</p> <p>23 A. Two percent.</p> <p>24 Q. And is that generally consistent</p>

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<p>1 with your understanding of the subjective 2 complication rates of pain, sexual 3 dysfunction and voiding dysfunction that 4 were reported for synthetic midurethral 5 slings in the clinical literature?</p> <p>6 A. Yeah, that's my understanding. 7 And acceptable is very 8 subjective type of a question. That's why 9 I have difficulty answering it.</p> <p>10 Q. So, even though you were 11 answering questions about specifically 12 asking about acceptable, would it be more 13 appropriate to consider those just kind of 14 general rates that are more commonly seen 15 in the literature?</p> <p>16 A. Yes, I would agree with that.</p> <p>17 Q. And are the complications that 18 you notice in your practice generally 19 consistent with the medical literature 20 related to synthetic midurethral slings?</p> <p>21 A. Yes, absolutely.</p> <p>22 Q. And what is that based on?</p> <p>23 A. So, that's based on my review of 24 the literature and seeing patients back</p>	<p>1 this earlier, this procedure, and not have 2 waited that long."</p> <p>3 Q. And do you track your 4 complications in more of an informal 5 basis?</p> <p>6 A. So, we track complications 7 formally. However, we don't write down 8 our complications all the time. We have 9 biweekly and/or monthly internal morbidity 10 and mortality meetings. Thank God we 11 don't have too many people who died from 12 our procedures, or it's pretty rare. But 13 we have morbidity where we talk about our 14 complications. We talk about the 15 complications that have come into the 16 office and/or have gone to the operating 17 room. So we do that on a formal and 18 informal basis. And if we have a serious 19 complication, that may get presented in 20 hospital M&M rounds. And M&M rounds are 21 protected by confidentiality.</p> <p>22 Q. And going back to the AUA 23 guideline that we are looking at. 24 The page showing suspensions in</p>
<p style="text-align: center;">Page 335</p> <p>1 postoperatively, as well as reports from 2 patients, seeing them in the long-term, 3 long-term patients returning to my office 4 for various reasons, as well as discussion 5 with other referring physicians, and 6 colleagues that would manage complications 7 if this -- if a patient came back to 8 another physician and then telling me. We 9 speak all the time and sometimes I even 10 ask have you seen any of my complications 11 recently.</p> <p>12 Q. And as I understand it, you may 13 not have a formal spreadsheet that tracks 14 all of your complications over the past 15 two decades.</p> <p>16 But how would you say you're 17 able to characterize your general 18 understanding of complication rates and 19 whether or not they're higher or lower 20 than what you would expect?</p> <p>21 A. I don't see a significant number 22 of women coming back in complaining of 23 pain and/or dyspareunia. Majority of the 24 women just say "I wish I would have done</p>	<p style="text-align: center;">Page 337</p> <p>1 the middle column Burch suspension.</p> <p>2 A. Yes.</p> <p>3 Q. What does it report for pain?</p> <p>4 A. So, pain was 6 percent, sexual 5 dysfunction is 3 percent, and voiding 6 dysfunction is 10 percent.</p> <p>7 Once again, difficult ways to 8 get pinned down of what's an acceptable 9 rate for anything.</p> <p>10 Q. And so, although those rates for 11 the Burch procedure with respect to pain, 12 sexual dysfunction, and voiding 13 dysfunction are higher than the reports 14 seen and the reports -- or the 15 complication rates that you discussed 16 earlier, that doesn't necessarily 17 automatically make those rates for that 18 procedure unacceptable; is that fair?</p> <p>19 A. That's fair. It's just 20 recording the rates, and nobody's making a 21 determination here of what's acceptable 22 and unacceptable.</p> <p>23 Q. And would it be fair to say that 24 rather than saying acceptable or</p>

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<p>1 unacceptable, you would always perform a 2 risk-benefit analysis?</p> <p>3 A. Right. So, with each individual 4 patient, you need to perform the 5 risk-benefit analysis of what's going to 6 be a more acceptable procedure risk-wise 7 for them.</p> <p>8 Q. And so, although I take it you 9 wouldn't necessarily consider the Burch 10 procedure to be an unsafe procedure, based 11 on your testimony, it sounds like after 12 performing a risk-benefit analysis with 13 your patients, they seldom select to 14 proceed with the Burch procedure; is that 15 fair?</p> <p>16 A. That is fair. And the clinical 17 data reports lower morbidity with 18 midurethral slings.</p> <p>19 Q. Looking under "Slings" where it 20 states: "Autologous fascia without bone 21 anchors."</p> <p>22 Do you see that?</p> <p>23 A. Yes, I do.</p> <p>24 Q. And if you go down to the</p>	<p>1 Q. Is that consistent with your 2 clinical practice?</p> <p>3 A. Yes, it is. (Exhibit Winkler 30, Schimpf article, was marked for identification, as of this date.)</p> <p>7 BY MR. ROSENBLATT:</p> <p>8 Q. I'm going to hand you what I've 9 marked as Exhibit 30, which is the Schimpf 10 meta-analysis.</p> <p>11 Doctor, are you familiar with 12 what's been marked as Exhibit 30?</p> <p>13 A. Yes, I am.</p> <p>14 Q. And is this the systematic 15 review performed by the Society of 16 Gynecologic Surgeons?</p> <p>17 A. Yes, it is, by a committee from 18 them.</p> <p>19 Q. Doctor, if you turn to table 3 20 reporting adverse events.</p> <p>21 What is the rate reported of 22 dyspareunia for retropubic midurethral 23 slings?</p> <p>24 A. It's 0 percent with a 95 percent</p>
<p style="text-align: center;">Page 339</p> <p>1 subjective complications, what are the 2 complications reported for the autologous 3 fascial sling, based on the AUA's 4 analysis?</p> <p>5 A. Ten percent for pain, 8 percent 6 for sexual dysfunction.</p> <p>7 Q. And then there's an asterisk for 8 voiding dysfunction where it states: 9 "Only case reports of this complication 10 exist and data are insufficient to 11 estimate the frequency."</p> <p>12 Do you see that?</p> <p>13 A. Yes, I do.</p> <p>14 Q. And so, based on the AUA's 15 analysis of the literature for synthetic 16 midurethral slings, autologous fascial 17 slings, and Burch, would it be fair to say 18 that pain, sexual dysfunction, voiding 19 dysfunction are typically lower with 20 synthetic midurethral slings?</p> <p>21 MR. BENTLEY: Objection; vague; 22 leading; compound.</p> <p>23 A. Yes, they're lower with the 24 midurethral sling.</p>	<p style="text-align: center;">Page 341</p> <p>1 confidence interval of .01 percent to 1.64 2 percent.</p> <p>3 Q. And for exposure, what is the 4 percentage listed for retropubic slings?</p> <p>5 A. Exposure retropubic slings is 6 1.4 percent.</p> <p>7 Q. And so, Doctor, although there 8 may be studies that show a higher rate or 9 a lower rate, do you rely on Level I 10 evidence such as systematic reviews like 11 the Schimpf review, in order to support 12 your opinions about generally accepted and 13 expected complication rates?</p> <p>14 A. Yes, I rely on the literature, 15 as well as my clinical experience.</p> <p>16 Q. Are the complications that you 17 see in your clinical experience generally 18 consistent with the Level I literature?</p> <p>19 A. Yeah, the complications that I 20 see are expected with the Level I 21 literature. (Exhibit Winkler 31, Ford Cochrane review, was marked for identification, as of this date.)</p>

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<p>1 BY MR. ROSENBLATT:</p> <p>2 Q. Handing you what I've marked as</p> <p>3 Exhibit 31, which is the Ford Cochrane</p> <p>4 review.</p> <p>5 Is this a review that you</p> <p>6 referenced in your report?</p> <p>7 A. Yes.</p> <p>8 Q. Doctor, this systematic review</p> <p>9 is based on 81 randomized control trials</p> <p>10 that evaluated over 12,000 women?</p> <p>11 A. Yes, that's accurate.</p> <p>12 Q. You recall being asked some</p> <p>13 questions about SPARC versus the TTVT?</p> <p>14 A. Yes, I do.</p> <p>15 Q. And the SPARC would be a</p> <p>16 top-down sling?</p> <p>17 A. Yes, it is.</p> <p>18 Q. And TTVT would be -- the TTVT and</p> <p>19 TTVT-Exact that we're talking about today</p> <p>20 would be a bottom-up approach?</p> <p>21 A. Yes, it is.</p> <p>22 Q. Do you see where it states: "A</p> <p>23 retropubic bottom-to-top route was more</p> <p>24 effective than top-to-bottom route for</p>	<p>1 "Midurethral sling operations have been</p> <p>2 the most extensively researched surgical</p> <p>3 treatment for stress urinary incontinence,</p> <p>4 SUI, in women and have a good safety</p> <p>5 profile."</p> <p>6 Do you see that?</p> <p>7 A. Yes, I do.</p> <p>8 Q. And is that consistent or</p> <p>9 inconsistent with your opinions in this</p> <p>10 case?</p> <p>11 A. That's consistent with my</p> <p>12 opinions.</p> <p>13 Q. Doctor, looking on page 10 of</p> <p>14 the Ford review, do you see where they</p> <p>15 describe synthetic meshes as being type 1,</p> <p>16 type 2, type 3, or type 4?</p> <p>17 A. Yes, I do.</p> <p>18 Q. And they describe type 1 as</p> <p>19 being macroporous and monofilament?</p> <p>20 A. Correct.</p> <p>21 Q. What is your understanding as to</p> <p>22 what type of mesh Prolene TTVT is?</p> <p>23 A. It's a macroporous monofilament</p> <p>24 mesh. It's a type 1.</p>
<p style="text-align: center;">Page 343</p> <p>1 subjective cure. It incurred</p> <p>2 significantly less voiding dysfunction and</p> <p>3 led to fewer bladder perforations and</p> <p>4 vaginal tape erosions."</p> <p>5 Do you see that?</p> <p>6 A. I see that and that's what I</p> <p>7 hold by today.</p> <p>8 Q. Would a systematic review, such</p> <p>9 as the Ford Cochrane review, look at more</p> <p>10 patients and more data than the 2011</p> <p>11 article that looked at 113 patients?</p> <p>12 A. Definitely. That is a much --</p> <p>13 the Cochrane review is a much higher level</p> <p>14 of evidence than my paper.</p> <p>15 Q. And when you're practicing</p> <p>16 evidence-based medicine, would you rely on</p> <p>17 the results of Cochrane review such as</p> <p>18 this Ford 2015 Cochrane review as opposed</p> <p>19 to one study?</p> <p>20 A. A hundred percent I would rely</p> <p>21 on the Cochran review over the one study,</p> <p>22 and that's how I practice today.</p> <p>23 Q. Doctor, the authors' conclusions</p> <p>24 for the Ford Cochran review states:</p>	<p style="text-align: center;">Page 345</p> <p>1 Q. That's a type 1 classification?</p> <p>2 A. Yes, it is.</p> <p>3 Q. And this is from 2015?</p> <p>4 A. Correct. Most recent Cochrane</p> <p>5 review on slings.</p> <p>6 Q. And it states a little further</p> <p>7 down: "Type 1 mesh has the highest</p> <p>8 biocompatibility with the least propensity</p> <p>9 for infection."</p> <p>10 Is that consistent or</p> <p>11 inconsistent with your opinion?</p> <p>12 A. That's consistent with my</p> <p>13 opinion.</p> <p>14 Q. Doctor, if you could pull out</p> <p>15 Exhibit 26, which is the study we were</p> <p>16 just comparing there.</p> <p>17 A. Yes, I got it.</p> <p>18 Q. This is a study where you were a</p> <p>19 co-author comparing Ethicon's TTVT to AMS's</p> <p>20 SPARC?</p> <p>21 A. Correct.</p> <p>22 Q. And on the last page, the last</p> <p>23 paragraph states: "In conclusion, both</p> <p>24 the suprapubic and the transvaginal</p>

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<p>1 procedures."</p> <p>2 Which would be the TVT.</p> <p>3 A. Correct.</p> <p>4 Q. (Continuing) "were associated</p> <p>5 with a significant improvement in quality</p> <p>6 of life as measured by the UDI-6."</p> <p>7 Do you see that?</p> <p>8 A. That is correct.</p> <p>9 Q. So they're not saying that there</p> <p>10 was a worsening of quality of life after</p> <p>11 TVT, but just that in this study with</p> <p>12 these patients, the SPARC had a higher</p> <p>13 increase in quality of life compared to</p> <p>14 the TVT.</p> <p>15 Is that accurate?</p> <p>16 A. That's accurate.</p> <p>17 Q. And under the "Discussion," the</p> <p>18 first paragraph it says: "The surgical</p> <p>19 management of stress incontinence has</p> <p>20 advanced from the Burch colposuspension</p> <p>21 and pubovaginal sling techniques to the</p> <p>22 newer midurethral approaches designed to</p> <p>23 achieve at least similar efficacy while</p> <p>24 reducing morbidity in postoperative</p>	<p>1 figure out causality.</p> <p>2 Q. In fact, in the conclusion it</p> <p>3 states: "Complication rates in new onset</p> <p>4 urinary urge incontinence were low in both</p> <p>5 groups"?</p> <p>6 A. Yes. And then we even write</p> <p>7 that the study design provided only Level</p> <p>8 III evidence.</p> <p>9 Q. Which would be lower than, say,</p> <p>10 a systematic review, right?</p> <p>11 A. Exactly. Lower than Level I,</p> <p>12 for sure.</p> <p>13 Q. And if you turn to the results</p> <p>14 page in the paragraph that starts:</p> <p>15 "Concomitant surgery was performed in 75.7</p> <p>16 percent of patients who underwent the</p> <p>17 suprapubic sling procedure." Which would</p> <p>18 be the TVT. And in 90 percent of the --</p> <p>19 or, the SPARC.</p> <p>20 A. Correct.</p> <p>21 Q. And in 90.7 percent of those who</p> <p>22 underwent the transvaginal procedure.</p> <p>23 A. Correct. So, those are all risk</p> <p>24 factors for having possibly decreased</p>
<p>1 recovery. Midurethral sling procedures</p> <p>2 are the most commonly performed</p> <p>3 anti-incontinence procedures and are safe</p> <p>4 and efficacious."</p> <p>5 Do you see that?</p> <p>6 A. Yes, I do.</p> <p>7 Q. And is that consistent or</p> <p>8 inconsistent with your opinions?</p> <p>9 A. Entirely consistent.</p> <p>10 Q. Although the authors on this</p> <p>11 paper were suggesting that there might be</p> <p>12 differences in the quality of life based</p> <p>13 on the needle size, you see at the bottom</p> <p>14 of the discussion here where it states:</p> <p>15 "It is unclear why a significantly greater</p> <p>16 improvement in UDI-6 was seen in the</p> <p>17 suprapubic treatment group"?</p> <p>18 A. Yes. We couldn't come up with a</p> <p>19 clear explanation.</p> <p>20 Q. So, would you use this study to</p> <p>21 definitively say that the needle size</p> <p>22 definitively was the cause for the</p> <p>23 increase or decrease in quality of life?</p> <p>24 A. Absolutely not. We could not</p>	<p>1 quality-of-life rates afterwards.</p> <p>2 Q. And if you look at table 1, it</p> <p>3 appears that the TVT group had more</p> <p>4 concurrent prolapse surgeries, more</p> <p>5 vaginal hysterectomies, more anterior</p> <p>6 repairs, more posterior repairs, more</p> <p>7 paravaginal repairs than the SPARC group.</p> <p>8 Is that accurate?</p> <p>9 A. That is correct.</p> <p>10 Q. Okay. You can put that aside.</p> <p>11 Doctor, looking at your report</p> <p>12 on page 26.</p> <p>13 A. Yes.</p> <p>14 Q. You were asked some questions</p> <p>15 about mesh characteristics, and I think</p> <p>16 you referred to the Moalli study.</p> <p>17 A. Yes.</p> <p>18 Q. Is this a chart from the Moalli</p> <p>19 study?</p> <p>20 A. Yes, it is.</p> <p>21 Q. Under "Mesh Type" it lists six</p> <p>22 different manufacturers.</p> <p>23 A. Yes, it does.</p> <p>24 Q. And Gynecare would be Ethicon?</p>

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<p>1 A. Yes.</p> <p>2 Q. And out of all of the</p> <p>3 manufacturers, which mesh had the largest</p> <p>4 pore size as described in the chart on</p> <p>5 Moalli?</p> <p>6 A. The largest pore size is the</p> <p>7 Ethicon Gynecare mesh.</p> <p>8 Q. And that shows 1,379 microns?</p> <p>9 A. Correct.</p> <p>10 Q. Compared to Boston Scientific's</p> <p>11 Advantage mesh which was 1,182 microns?</p> <p>12 A. Correct.</p> <p>13 Q. But it looks like the fiber size</p> <p>14 with respect to diameter was the same for</p> <p>15 TTV versus Advantage mesh?</p> <p>16 A. That's correct.</p> <p>17 Q. And the weight is similar at 100</p> <p>18 grams per meter squared for TTV versus the</p> <p>19 Advantage mesh?</p> <p>20 A. Yes, that's true.</p> <p>21 Q. And the Advantage mesh made by</p> <p>22 Boston Scientific has a laser or a</p> <p>23 heat-sealed portion under the midurethra?</p> <p>24 A. That is correct.</p>	<p>1 mechanically-cut versus laser-cut?</p> <p>2 A. I have not noticed an increase</p> <p>3 or decrease in the complications or</p> <p>4 patients returning for complications based</p> <p>5 on either.</p> <p>6 Q. And is there any reliable</p> <p>7 peer-reviewed clinical literature that has</p> <p>8 confirmed that there is a difference?</p> <p>9 A. There is no reliable literature</p> <p>10 that I'm aware of that has confirmed that.</p> <p>11 Q. And so, although there may be</p> <p>12 studies where authors suggest, such as in</p> <p>13 your paper where you're describing what</p> <p>14 might be the cause for something, that</p> <p>15 doesn't definitively establish causation,</p> <p>16 correct?</p> <p>17 A. No, it does not, correct.</p> <p>18 Q. I believe you testified that</p> <p>19 biologic slings don't have substantial</p> <p>20 efficacy as reported by clinical</p> <p>21 literature?</p> <p>22 A. That's true.</p> <p>23 Q. And so, would it be accurate or</p> <p>24 inaccurate to refer to biologic slings for</p>
<p style="text-align: center;">Page 351</p> <p>1 Q. And then the rest of the sling</p> <p>2 would be what we call a tanged or</p> <p>3 mechanically-cut?</p> <p>4 A. Correct.</p> <p>5 Q. Have you ever noticed any</p> <p>6 particle loss with the tanged or</p> <p>7 mechanically-cut portion of the Advantage</p> <p>8 mesh?</p> <p>9 A. I have not noticed any.</p> <p>10 Q. Have you noticed any</p> <p>11 complications or any problems with</p> <p>12 particle loss roping, fraying, curling,</p> <p>13 degradation or cytotoxicity related to the</p> <p>14 TTV mesh?</p> <p>15 A. No, I have not.</p> <p>16 Q. And regardless of whether the</p> <p>17 TTV at the time you were using it was TTV</p> <p>18 mechanically-cut or TTV laser-cut?</p> <p>19 A. Regardless, they were both the</p> <p>20 same.</p> <p>21 Q. And although you don't have a</p> <p>22 spreadsheet tracking the complications,</p> <p>23 throughout your career, have you noticed a</p> <p>24 difference in the complications between</p>	<p style="text-align: center;">Page 353</p> <p>1 primary incontinence as the gold standard?</p> <p>2 A. They are not the gold standard.</p> <p>3 It would be inaccurate to refer to</p> <p>4 biologic slings as the gold standard.</p> <p>5 Q. And most of the long-term data</p> <p>6 that exists for TTV, is that on the</p> <p>7 laser-cut or the mechanically-cut?</p> <p>8 A. The long-term data is mostly on</p> <p>9 the mechanically-cut.</p> <p>10 Q. You talked about having to</p> <p>11 perform release procedures after</p> <p>12 midurethral slings.</p> <p>13 You recall those questions?</p> <p>14 A. Yes, I do.</p> <p>15 Q. Have you had to perform similar</p> <p>16 release procedures for autologous fascial</p> <p>17 slings or biologic slings?</p> <p>18 A. Well, for the autologous fascial</p> <p>19 slings, the procedure for voiding</p> <p>20 dysfunction actually is a little more</p> <p>21 difficult. Usually instead of just</p> <p>22 incising the sling, you would do a full</p> <p>23 urethrolysis where you would go in and</p> <p>24 either cut the sling on both sides and go</p>

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<p>1 behind the urethra and dissect behind to 2 take down some of the scarring that occurs 3 with the pubovaginal sling. 4 Q. Doctor, jumping around a little 5 bit, we were talking about levels of 6 evidence and the Oxford levels. 7 Do you recall that? 8 A. Yes, I do. 9 Q. How does the quality of evidence 10 on Burch and autologous fascial slings and 11 biologic slings compare to the quality and 12 volume of evidence on TVT and synthetic 13 midurethral slings? 14 A. The quality and volume of 15 evidence on TVT slings is significantly 16 more on those than on Burch and 17 pubovaginal slings and better quality and 18 more evidence. 19 Q. When you were asked questions 20 about Dr. Rosenzweig's opinions on 21 mechanically-cut versus laser-cut, did 22 you, in fact, go through and review Dr. 23 Rosenzweig's expert report as well as the 24 materials that he cited in the body of his</p>	<p>1 A. Yes, I do. 2 Q. In this column, what did they 3 show as far as whether there were any mesh 4 particles in the muscle? 5 A. There was no evidence of such. 6 MR. BENTLEY: Is it marked? 7 MR. ROSENBLATT: No. Do you 8 want me to mark it? 9 MR. BENTLEY: I don't know. I 10 just thought that -- 11 MR. ROSENBLATT: I was just 12 going to try to wrap up. 13 MR. BENTLEY: That's fine. 14 BY MR. ROSENBLATT: 15 Q. Doctor, you also brought with 16 you a photograph. 17 A. This one (indicating)? 18 Q. Exhibit 25. 19 Why did you bring this 20 photograph with you? 21 A. I wanted to show that roping and 22 curling, even with erosions, does not 23 occur. Usually it would, and the mesh is 24 not shrinking and contracting. It's just</p>
<p>1 report? 2 A. Yes, I did. 3 Q. And did any of those materials 4 change your opinions? 5 A. No, they did not. 6 Q. You were asked about your 7 presentation that showed a image of mesh 8 being similar to reinforced concrete. 9 Do you recall that? 10 A. Yes, I do. 11 Q. Were you in any way trying to 12 suggest that mesh is difficult to remove 13 like rebar might be difficult to remove 14 from concrete? 15 A. Absolutely not. It was just a 16 philosophical type of explanation of what 17 the mesh does. 18 Q. Was it more so just to describe 19 the scaffolding and how the mesh works by 20 providing support? 21 A. Yes, it was. 22 Q. Doctor, do you recall reviewing 23 a rabbit study where Ethicon looked for 24 mesh particles within the muscle?</p>	<p>1 being exposed out. 2 Q. And how would you describe the 3 pore size of that TVT mesh? 4 A. Without a ruler, it looks pretty 5 similar to how we put it in and above a 6 millimeter. 7 Q. Does it look to be an open pore 8 or a collapsed pore? 9 A. It's an open pore. 10 Q. Doctor, I believe you had 11 testified a little bit about your 12 experience with companies and industry. 13 Have you consulted with industry 14 on safety of products and devices with 15 respect to warnings, as well as design? 16 A. Yes, I have. 17 Q. And did you describe some of 18 that experience throughout your 19 deposition? 20 A. Yes, I have. 21 Q. Doctor, on page 37 -- I'm sorry, 22 38 of your report. 23 A. Okay. 24 Q. If you could turn there for me.</p>

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<p>1 The last paragraph you reference 2 the AUGS urogynecology resident 3 objectives. 4 Do you see that? 5 A. Yes. 6 Q. On the next page, the last 7 sentence says: "The resident should be 8 able to discuss risk, benefits, expected 9 outcomes of non-surgical and surgical 10 management of SUI." 11 Do you see that? 12 A. Yes, I do. 13 Q. You also identify the 2012 ABOG 14 and ABU guidelines for earning an FPMRS? 15 A. Yes, I do. 16 Q. You go through in your report 17 and identify some other documents that 18 you're relying upon. 19 Are these just some of the 20 documents that you're relying on to 21 demonstrate what surgeons are expected to 22 know? 23 A. Yeah, these are some of them. 24 Q. And so although you may not know</p>	<p>1 of mechanically-cut versus laser-cut. 2 Q. And are all of the opinions that 3 you've offered in your report, as well as 4 here today, held to a reasonable degree of 5 medical certainty? 6 A. Yes, they are. 7 MR. ROSENBLATT: No further 8 questions. 9 FURTHER EXAMINATION BY 10 MR. BENTLEY: 11 Q. Doctor, you testified that you 12 wouldn't want to hide your affiliation or 13 work with industry. 14 Do you remember that? 15 A. Yes. 16 Q. And you -- 17 A. And I -- any time if I was 18 required to disclose it, I did disclose 19 it. 20 Q. In your report for this matter 21 discussing the TVT and TVT-Exact, you note 22 that you've worked for industry, right? 23 A. Yes. 24 Q. And why in your report do you</p>
<p style="text-align: center;">Page 359</p> <p>1 exactly what every surgeon does or does 2 not know, what is your opinion as to what 3 surgeons should be expected to know about 4 commonly known complications? 5 MR. BENTLEY: Objection. 6 A. Surgeons should be expected to 7 know that based on their education, 8 training, and reading of the literature, 9 as well as maintenance of certification. 10 Q. Doctor, you testified that 11 you're currently performing for your 12 retropubic slings either Boston 13 Scientific's Advantage mesh or the 14 TVT-Exact. 15 A. Correct. 16 Q. Does the fact that you're not 17 currently performing TVT mechanically-cut, 18 is that based on any concerns that you 19 have about the safety of TVT 20 mechanically-cut? 21 MR. BENTLEY: Objection. 22 A. That's not based on any of the 23 concerns. I have not seen a noticeable 24 difference, nor is it reported clinically,</p>	<p style="text-align: center;">Page 361</p> <p>1 not discuss that you've worked for Ethicon 2 who's hired you to act as their expert in 3 this case? 4 A. I don't put any of my expert 5 witness information on my CV. I've done 6 expert witness for medical malpractice, 7 and I haven't put that on my CV. 8 Q. I'm talking about in your TVT 9 and TVT-Exact report in which you disclose 10 that you've worked for industry, right? 11 A. Yes. 12 Q. Okay. In your TVT and TVT-Exact 13 report, is there any reason why you don't 14 disclose that you've previously consulted 15 and taught for Ethicon? 16 A. Did I write in my report that I 17 specifically consulted for other 18 companies? I don't think I did that. Why 19 should I single one out. 20 Q. That wasn't my question. 21 Is there any reason why you 22 didn't disclose in your report regarding 23 TVT and TVT-Exact that you have 24 specifically consulted for the</p>

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<p>1 manufacturers of these products?</p> <p>2 A. There's no reason for that.</p> <p>3 And it explicitly says in my</p> <p>4 report my fee schedule, and everyone in</p> <p>5 the jury or everyone will know exactly</p> <p>6 what I'm getting paid and how much I'm</p> <p>7 getting paid, and you have my invoices.</p> <p>8 Q. If you were going to update your</p> <p>9 report, would you want to include any</p> <p>10 information about your previous consulting</p> <p>11 work with Ethicon?</p> <p>12 A. I don't -- if -- I don't think</p> <p>13 that's required in the report. It's</p> <p>14 not -- it's disclosable and I'm telling</p> <p>15 you about it, but the report is really</p> <p>16 based on my review of the literature and</p> <p>17 my clinical experience today, not money</p> <p>18 that I received 15 years ago.</p> <p>19 Q. When you were updating your</p> <p>20 resume around 2013 and you went and added</p> <p>21 a lot of the earlier 2000 AMS and Boston</p> <p>22 Scientific work, how did you remember to</p> <p>23 add that information in 2013?</p> <p>24 A. Some of that stuff I had written</p>	<p>1 Scientific?</p> <p>2 A. No, I don't have notes. I have</p> <p>3 just some labs that I went to and what was</p> <p>4 there. I don't have specific -- I have</p> <p>5 little tidbits here and there, and I have</p> <p>6 some of that, but I don't have it all,</p> <p>7 unfortunately.</p> <p>8 Q. When you did the updates in</p> <p>9 2013, that was just based off your memory,</p> <p>10 your recollection of what happened in the</p> <p>11 early 2000s?</p> <p>12 A. It was based on my -- most of it</p> <p>13 was based on my recollection, yes.</p> <p>14 Q. And you didn't recall that you</p> <p>15 had also done work for Ethicon?</p> <p>16 A. No, I never denied that I was a</p> <p>17 preceptor for Ethicon. I don't recall</p> <p>18 doing any kind of labs for Ethicon.</p> <p>19 Q. We looked at your study that was</p> <p>20 comparing SPARC to TVT, and I believe your</p> <p>21 explanation for not including that in your</p> <p>22 report was because it was Level III</p> <p>23 evidence.</p> <p>24 Was that correct?</p>
<p style="text-align: center;">Page 363</p> <p>1 with some papers and whatnot.</p> <p>2 There was a time when me and my</p> <p>3 partner were combining our stuff that we</p> <p>4 did. There was a time that I was</p> <p>5 recording it and there was a time that he</p> <p>6 was recording it, or we had somebody else</p> <p>7 recording it, and some of that stuff I had</p> <p>8 written, but I didn't have all of it</p> <p>9 recorded. And then we stopped doing that</p> <p>10 as well.</p> <p>11 Q. When did you first --</p> <p>12 A. But I don't -- I mean, if I -- I</p> <p>13 don't recall, and it's possible I may have</p> <p>14 taught one, but I did not do any</p> <p>15 significant cadaver labs for Gynecare. I</p> <p>16 may have done one or two, I don't recall</p> <p>17 those, and those are what I put on my CV</p> <p>18 because those are teaching labs to --</p> <p>19 that's teaching experience to multiple</p> <p>20 doctors.</p> <p>21 Q. I think you're testifying that</p> <p>22 you have notes or you had notes in 2013</p> <p>23 documenting a lot of the work you did in</p> <p>24 the early 2000s for AMS and Boston</p>	<p style="text-align: center;">Page 365</p> <p>1 A. You're talking about my report</p> <p>2 for --</p> <p>3 Q. Your report that found that AMS</p> <p>4 product had a higher quality of life</p> <p>5 compared to the TVT Retropubic.</p> <p>6 Remember that?</p> <p>7 A. Yeah, I do.</p> <p>8 First of all, I thought it was</p> <p>9 low-quality evidence, and there was</p> <p>10 nothing in that report that would show</p> <p>11 that either of the slings, which are very,</p> <p>12 very similar, was defective.</p> <p>13 Q. And my question is did you</p> <p>14 include other Level III evidence in your</p> <p>15 TVT report?</p> <p>16 A. I may have. However, I -- once</p> <p>17 again, if Level I data is available, I</p> <p>18 would try to include the Level I data. If</p> <p>19 there's no Level I data, I would go to 2</p> <p>20 and then I would go to 3.</p> <p>21 Q. I believe you testified that</p> <p>22 Prolene is a type 1 macroporous mesh,</p> <p>23 right?</p> <p>24 A. I think I testified that TVT is</p>

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<p>1 a type 1 macroporous mesh, not Prolene. 2 Q. You understand that TVT is made 3 from Ethicon's Prolene mesh, do you? 4 A. I understand that. But you can 5 weave Prolene differently. You can make 6 the pores smaller. 7 So that's why I want to be 8 specific we're talking about that. 9 Q. It's confusing. 10 Prolene is the name of a suture, 11 right? 12 A. Yes. 13 Q. And then the mesh construction 14 that's in the TVT product that Ulmsten 15 originally used and it's still -- 16 A. It's called the Prolene mesh, I 17 agree with you. 18 Q. And that Prolene mesh is 19 considered type 1 macroporous per the Amid 20 classifications? 21 A. If we're talking about the 22 Prolene mesh. 23 Q. Right. 24 A. Yes.</p>	<p>1 there was some problems removing the 2 sheath using the ULTRAPRO mesh. I think 3 in the sterilization process, the plastic 4 got stuck to the mesh. So I think Ethicon 5 was trying to see if there were 6 alternatives to their mesh there. 7 There's also a study noted in my 8 report comparing the TVT -- comparing a 9 heavier-weight mesh, which you pointed out 10 to me, to a lighter-weight mesh, and the 11 lighter-weight mesh didn't perform as well 12 as the heavier-weight mesh. 13 Q. And by "perform," you're talking 14 about its ability to effectively treat 15 incontinence; is that correct? 16 A. So, I'm referencing the 17 Prien-Larsen study published a prospective 18 study comparing the 100 gram meters 19 squared with low stiffness and rough edges 20 to lighter weight 60 grams per meters 21 squared, and in 12 months there was a 22 significant difference in objective cure 23 rates favoring the heavier-weight mesh 86 24 versus 96 percent.</p>
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<p>1 Q. Do you understand that that mesh 2 was created for application in hernia 3 repair? 4 A. Yes, I do. 5 Q. And do you understand Ethicon 6 subsequently made newer meshes, such as 7 Prolene Soft? 8 A. Yes, I'm aware of that. 9 Q. And subsequently Ethicon's made 10 ULTRAPRO also, which is I think a softer 11 mesh with a partially absorbable 12 component? 13 A. Correct. 14 Q. And those meshes are actually 15 lighter weight than the original Prolene 16 mesh that's used in TVT? 17 A. That's correct. 18 Q. And Ethicon never updated the 19 TVT mesh with those newer meshes, correct? 20 A. Well, from the data, I think 21 they actually looked at using ULTRAPRO in 22 their mesh and they submitted to the FDA 23 and that was denied by the FDA. 24 And if I remember correctly,</p>	<p>1 Q. Right. And I'm just trying to 2 see do you understand that the purpose of 3 going to a lighter-weight mesh is to 4 reduce the histological response after 5 implantation? 6 A. I understand that's the purpose, 7 but you need to maintain the efficacy as 8 well still. 9 Q. Do you have an opinion of 10 whether Prolene Soft has a less 11 inflammation response as compared to 12 Prolene original that's in TVT? 13 MR. ROSENBLATT: Object to form. 14 A. The Prolene Soft fiber is a 15 smaller fiber than the fiber used in the 16 TVT mesh. There has -- and so that may 17 result in a reduced chronic inflammatory 18 reaction, but once again clinically, we 19 don't see any clinical evidence from this 20 chronic inflammatory reaction with the 21 heavier-weight mesh. 22 Q. Doctor, you mentioned a couple 23 of avenues by which physicians should know 24 about different complications, and I think</p>

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<p>1 you talked about the literature and their 2 training. 3 Do you remember that? 4 A. Yes, I do. 5 Q. And do you understand that one 6 of the purposes of the IFU is to provide 7 another avenue of information for 8 physicians? 9 A. Yes, the IFU can provide another 10 avenue. 11 Q. It's actually written for 12 physicians, right? 13 A. Correct, it's written for the 14 physicians. 15 Q. Are you still working as a 16 consultant for Ethicon regarding product 17 design or -- 18 A. No, only for the expert work. 19 Q. When did your consulting, your 20 non-litigation consulting work end with 21 Ethicon? 22 A. So, I don't remember exactly. I 23 don't have the contracts anymore, anything 24 like that.</p>	<p>1 later. 2 Q. Would you like to have a 3 complete record of your work for Ethicon 4 now that it's refreshed your memory that 5 you worked for them? 6 A. I mean, to me it's past history. 7 So, you can give it to me. I don't think 8 it's going to change any of my opinions 9 today. I'm going to go with what the data 10 supports today. 11 I do expect to be paid for my 12 time away from my family and away from 13 leisure time watching T.V. And, you know, 14 thing are expensive. That's just -- got 15 to pay for the kids. 16 Q. When you testify before a jury, 17 would you like to be able to provide a 18 full and accurate description of your 19 previous consulting work with Ethicon so 20 the jury can know that? 21 A. I don't have a problem giving 22 that information to them. 23 Q. So you'd want to know that? 24 A. I didn't say that. I said I</p>
<p style="text-align: center;">Page 371</p> <p>1 Somewhere probably in the 2 mid-2000s, '6, '7 -- probably '7, '8, 3 somewhere around there. 4 Q. Definitely not after 2010? 5 A. I don't think so. 6 Like I said, I don't have the 7 contracts, so I don't know. 8 Q. Do you have the ability to find 9 out that information if you wanted to know 10 it? 11 A. I don't think I have the 12 ability. 13 You have the ability though. 14 Q. Have you asked Ethicon to 15 provide you with that information so you 16 can know when you were consulting for 17 them? 18 A. I didn't ask them to 19 specifically provide that because I know 20 that I consulted for them and did 21 preceptorships for them and went to an 22 advisory board for that which I was 23 actually shown that I was at for 24 Gynemesh PS, which I'm sure will come out</p>	<p style="text-align: center;">Page 373</p> <p>1 wouldn't have a problem giving them that 2 information. 3 MR. BENTLEY: Thank you, Doctor. 4 MR. ROSENBLATT: Greg, if you 5 want to mark his training history and 6 go through that with him. 7 MR. BENTLEY: I mean, it was in 8 my document request. I don't know if 9 it was in the stuff that I was 10 produced. I tried to find it. And 11 that's part of the problem is there's 12 a lot of work and there's a lot of 13 gaps in it and I just don't know. 14 THE WITNESS: Do you want to go 15 off the record for a second? 16 MR. BENTLEY: That actually 17 needs to be on the record. 18 I'm good. I have no further 19 questions. 20 THE WITNESS: Okay. 21 MR. ROSENBLATT: Just briefly. 22 FURTHER EXAMINATION BY 23 MR. ROSENBLATT: 24 Q. Doctor, what was the purpose</p>

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<p>1 of--</p> <p>2 MR. ROSENBLATT: Strike that.</p> <p>3 Q. Doctor, what was your</p> <p>4 understanding of the purpose as to why you</p> <p>5 were teaching various professional</p> <p>6 education courses and preceptorships for</p> <p>7 various companies, including Gynecare,</p> <p>8 Ethicon?</p> <p>9 A. Okay. So, there were a couple</p> <p>10 of reasons.</p> <p>11 First of all, I believe that we</p> <p>12 need to continue furthering our physicians</p> <p>13 and making sure that they are doing</p> <p>14 procedures safely. I think you want a</p> <p>15 high-volume surgeon teaching these</p> <p>16 procedures to others that may have not had</p> <p>17 as much experience with them. So I</p> <p>18 believe in the continuing medical</p> <p>19 education.</p> <p>20 It is very hard for an attending</p> <p>21 doctor to learn new procedures that are</p> <p>22 out there. They need to -- there are</p> <p>23 resources, there's money that needs to be</p> <p>24 spent, there's time away from the</p>	<p>1 biases your opinions that you've offered</p> <p>2 in your report?</p> <p>3 A. No, I do not.</p> <p>4 MR. ROSENBLATT: No further</p> <p>5 questions.</p> <p>6 MR. BENTLEY: Thank you, Doctor.</p> <p>7 (Exhibit Winkler 32, Ethicon</p> <p>8 Inc. Johnson & Johnson report dated</p> <p>9 March 3, 2003, was marked for</p> <p>10 identification, as of this date.)</p> <p>11 (Deposition adjourned at 3:55 p.m.)</p>
<p>1 practice, and I wanted to be that</p> <p>2 resource.</p> <p>3 Specifically, also, if there</p> <p>4 were people locally wanting to learn this</p> <p>5 procedure, I wanted people to come to my</p> <p>6 OR and for me to meet these people</p> <p>7 learning this procedure so we can develop</p> <p>8 relationships and referral patterns as</p> <p>9 well. There was benefit to me as well and</p> <p>10 getting a reputation out there as being a</p> <p>11 leading expert also when I taught these</p> <p>12 procedures. If they had a tough patient</p> <p>13 that they would not want to operate on, I</p> <p>14 welcomed the referral.</p> <p>15 MR. BENTLEY: I'm sorry. I was</p> <p>16 going to lodge an objection to the</p> <p>17 extent it called for speculation.</p> <p>18 And I'm going to object to the</p> <p>19 response to the extent it exceeded the</p> <p>20 question as non-responsive.</p> <p>21 MR. ROSENBLATT: Okay.</p> <p>22 BY MR. ROSENBLATT:</p> <p>23 Q. Doctor, do you believe that your</p> <p>24 previous consulting experience in any way</p>	<p>1 Page 375</p> <p>2</p> <p>3 A C K N O W L E D G M E N T</p> <p>4</p> <p>5 STATE OF)</p> <p>6 :ss</p> <p>7 COUNTY OF)</p> <p>8</p> <p>9 I, HARVEY A. WINKLER, M.D., hereby</p> <p>10 certify that I have read the transcript of</p> <p>11 my testimony taken under oath in my</p> <p>12 deposition of March 12, 2017; that the</p> <p>13 transcript is a true and complete record</p> <p>14 of my testimony, and that the answers on</p> <p>15 the record as given by me are true and</p> <p>16 correct.</p> <p>17</p> <hr/> <p>18 HARVEY WINKLER, M.D.</p> <p>19 Signed and subscribed to before me this</p> <p>20 _____ day of _____, 2017.</p> <hr/> <p>21</p> <p>22</p> <p>23 Notary Public, State of</p> <p>24</p>

	Page 378	Page 380
1	E R R A T A	LAWYER'S NOTES
2	PAGE / LINE / CHANGE / REASON	PAGE / LINE
3	_____	_____
4	_____	_____
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1	C E R T I F I C A T E	
2	STATE OF NEW YORK	
3	COUNTY OF NEW YORK	
4		
5	I, Marie Foley, RMR, CRR, a	
6	Certified Realtime Reporter and Notary	
7	Public within and for the State of New	
8	York, do hereby certify:	
9	THAT HARVEY A. WINKLER, M.D., the	
10	witness whose deposition is hereinbefore	
11	set forth, was duly sworn by me and that	
12	such deposition is a true record of the	
13	testimony given by the witness.	
14	I further certify that I am not	
15	related to any of the parties to this	
16	action by blood or marriage, and that I am	
17	in no way interested in the outcome of	
18	this matter.	
19	IN WITNESS WHEREOF, I have	
20	hereunto set my hand this 15th day of	
21	March, 2017.	
22		
23		
24	MARIE FOLEY, RMR, CRR	